

1 TITLE PAGE

A Phase 1b/2a Multicenter Study of NOX66 and External Beam Radiotherapy in Patients with Metastatic Castration-resistant Prostate Cancer and Other Solid Tumors

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Quality Assurance Statement

This study was performed in accordance with The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6.

Confidentiality Statement

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4 LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Term	Definition
AE	Adverse event
CRF	Case report form
CTCAE	Common Terminology Criteria for Adverse Events
DLT	Dose-limiting toxicity
EBRT	External beam radiotherapy
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
Gy	Gray
mCRPC	Metastatic castration-resistant prostate cancer
MTD	Maximum tolerated dose
NCI	National Cancer Institute
NOX66	Idronoxil suppository
PK	Pharmacokinetic(s)
PSA	Prostate-specific antigen
QoL	Quality of life
RP2D	Recommended Phase 2 dose
SAE	Serious adverse event
SSC	Safety Steering Committee
TEAE	Treatment-emergent adverse event
TESAE	Treatment-emergent serious adverse event

9 INVESTIGATIONAL PLAN

9.1 Overall Study Design and Plan: Description

This was to be a Phase 1b/Phase 2a, open-label, multicenter study to determine the safety, tolerability, recommended Phase 2 dose (RP2D), efficacy, pharmacokinetics (PK) and pharmacodynamic (PD) properties of idronoxil when rectally administered as a suppository (NOX66) to patients with any solid tumor in Part 1 (dose escalation) who were eligible for low-dose external beam radiotherapy (EBRT) for at least one symptomatic or minimally symptomatic lesion (for the prevention of symptoms). At least 2 patients enrolled in Dose Cohorts 2 to 4 were to have metastatic castration-resistant prostate cancer (mCRPC). A Safety Steering Committee (SSC) reviewed available safety data after the first cycle (21 days) of each dose cohort of NOX66 in Part 1 to determine the maximum tolerated dose (MTD)/RP2D.

Approximately 30 patients with any solid tumor who required low-dose EBRT were to be enrolled sequentially to 4 planned NOX66 dose groups: Dose Cohort 1 at 800 mg (3 to 6 patients); Dose Cohort 2 at 1200 mg; Dose Cohort 3 at 1600 mg; and Dose Cohort 4 at 2400 mg (3 to 8 patients in each of Dose Cohorts 2 to 4). The total daily dose was administered twice a day. No intra-subject dose escalation was allowed.

In Cycle 1, NOX66 was administered for 14 days followed by a 7-day rest period on a 21-day cycle. From Cycle 2 onward, NOX66 was administered for 7 days followed by a 7-day rest period on a 14-day cycle. Patients continued to receive NOX66 on a cyclical basis until disease progression, unacceptable toxicity, withdrawal of consent, start of a new anticancer therapy, withdrawal of the patient by the investigator, or until the defined study end was reached.

The dose level of EBRT was either 8 Gray (Gy) as a single fraction or 20/25 Gy as 5 fractions given over 5 to 10 days. The first EBRT dose fraction was to be administered on Day 2 of Cycle 1 with the remaining dose fractions given between Day 3 and Day 11. The choice of one of the EBRT dose/fractions was at the discretion of the investigator and determined by the clinical requirements of the patient. EBRT was administered according to the institutional protocol.

All patients were closely monitored for any dose-limiting toxicities (DLTs) up to Day 21 of Cycle 1.

Dose escalation was based on an adapted “3+3” design, where dose cohorts were to be expanded for up to 6 patients (Dose Cohort 1) in the event of DLT or up to 8 patients (Dose Cohorts 2 to 4) to allow for robust estimation of PK parameters after being deemed “safe” based on the traditional “3+3” design.

At each dose level, 3 patients were initially treated with NOX66.

- If none of the first 3 patients enrolled in Cohort 1 experienced a DLT during the first treatment cycle, the dose was to be escalated to the next level.

- If none of the first 3 patients experienced a DLT during the first treatment cycle of Cohorts 2 to 4, then the dose level was to be deemed “safe” and up to 5 additional patients enrolled to the current dose level for estimation of PK parameters. At the same time (with the exception of Cohort 4), the next dose level was to be initiated and the first 3 patients enrolled to the escalated dose.
- If 1 of 3 patients experienced a DLT, an additional 3 patients were to be enrolled. If 1 of 6 patients experienced a DLT then this dose level was to be deemed “safe” and, for Cohorts 2 to 4, 2 more patients may have been enrolled for estimation of PK parameters. At the same time, the next dose level was to be initiated and the first 3 patients enrolled to the escalated dose.
- If > 1 of 3 or > 1 of 6 patients experienced a DLT, dose escalation was to be halted and the previous dose declared as the MTD.

If the 1200 mg dose was not tolerable (i.e., 2 or more patients with DLTs), an additional 3 patients were to be enrolled in the 800 mg dose cohort to declare 800 mg as the MTD (if no more than 1 of 6 patients experienced a DLT).

If no DLT was observed at 2400 mg (Dose Cohort 4), dose escalation was to be stopped and 2400 mg declared the RP2D.

There was a temporary halt for enrollment after the first 3 patients were enrolled in each cohort until the SSC cleared the dose level as safe to continue the dose escalation. During the SSC meeting for NOX66 dose escalation decision, the safety and tolerability of both EBRT doses (8 Gy and 20/25 Gy) was also evaluated.

Assessment of DLTs

A DLT was defined as an AE that occurred during Cycle 1 (Day 1 to Day 21) that was assessed as unrelated to the disease, intercurrent illness or concomitant medications and that, despite optimal therapeutic interventions, met any of the following criteria (judged to be associated with NOX66 alone or in combination with EBRT [possibly, probably or definitely related to]):

- Grade 3 or higher non-hematological toxicities (excluding alopecia) with the following exceptions:
 - Grade 3 nausea/vomiting or diarrhea < 72 hours with adequate antiemetic and other supportive care
 - Grade 3 fatigue < 1 week
 - Grade 3 or higher electrolyte abnormality that lasts 24 to 72 hours, was not clinically complicated, and resolved spontaneously or responded to conventional medical drugs
- Grade 4 non-hematologic (non-laboratory) toxicity of any duration.
- Grade 3 or Grade 4 febrile neutropenia of any duration.

- Grade 4 neutropenia or thrombocytopenia > 5 days.
- Grade 3 thrombocytopenia with bleeding.
- Grade 3 thrombocytopenia in combination with a Grade 3 or greater blood and lymphatic system disorder.
- Grade 3 AST or ALT that was associated with a Grade 2 or greater rise in bilirubin that lasted for more than 7 days.
- Any AST or ALT > 8 x ULN regardless of duration (5 to 8 x ULN for up to 2 weeks was allowed).
- Any AE that resulted in a treatment delay or hold of > 14 days.

Grading of DLTs followed the guidelines provided by the National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) v5.0.

All AEs of the grades specified above counted as DLTs unless they were clearly and incontrovertibly due to disease progression or extraneous causes.

After all patients enrolled in a cohort completed Cycle 1, and the data from these patients were available, a dose escalation meeting was conducted. At least 3 evaluable patients were required to proceed with DLT evaluation for each cohort.

The criteria for determination of an evaluable patient for a dose escalation decision or determination of the MTD, must have included:

- Patient who experienced a DLT during the 21-day treatment cycle (Cycle 1), or
- Patient who had not experienced a DLT and had taken at least 80% of the prescribed daily doses of NOX66 and completed all safety evaluations.

For each dose escalation cohort, additional patients may have been enrolled or replaced if a patient discontinued prior to the completion of Cycle 1 for reasons other than safety. Patients who developed a DLT and discontinued treatment were not replaced.

If a patient developed any DLT during Cycles 2 to 6, these were considered “DLT-equivalent toxicity” and recorded in the eCRF. This information may have been considered during SSC review to assess dose escalation.

Plans for cohort expansion (Part 2) and evaluation of pharmacokinetics were described in the protocol.

Dose escalation progressed through the first 3 planned dose levels before the Sponsor decided to terminate the study early in May 2023 for business reasons; the decision was not based on any safety concerns with NOX66. The results are therefore provided as an abbreviated study report.

The protocol is provided in [Appendix 16.1.1](#) and a sample case report form (CRF) is provided in [Appendix 16.1.2](#).

9.8 Changes in the Conduct of the Study or Planned Analyses

The first patient was enrolled under Protocol Version 3.0 (21 January 2022). The final version of the protocol was Version 4.0 (23 November; [Appendix 16.1.1.1](#)). The changes from Version 3.0 to Version 4.0 are summarized in [Appendix 16.1.1.2](#).

10 STUDY PATIENTS

10.1 Disposition of Patients

Thirty patients were screened, 9 were screen failures, and 21 were treated with NOX66: 4 with 800 mg, 7 with 1200 mg, and 10 with 1600 mg.

Reasons for treatment discontinuation and study discontinuation are summarized in [Table 1](#). The most frequent reason for treatment discontinuation was progressive disease (8 patients, 38.1%). The most frequent reasons for study discontinuation were death and study termination by the Sponsor (each 7 patients, 33.3%).

Patient disposition is shown in Listing [16.2-1](#) and survival follow-up is shown in Listing [16.2-7.8](#).

Table 1. Patient Disposition

	NOX66 Dose Escalation			Total N = 21 n (%)
	800 mg N = 4 n (%)	1200 mg N = 7 n (%)	1600 mg N = 10 n (%)	
Treated with NOX66	4	7	10	21
Primary reason for end of treatment				
Unacceptable toxicity	0	0	1 (10.0)	1 (4.8)
Adverse event	0	0	1 (10.0)	1 (4.8)
Death	0	2 (28.6)	1 (10.0)	3 (14.3)
Non-compliance with study drug	0	1 (14.3)	0	1 (4.8)
Progressive disease	3 (75.0)	3 (42.9)	2 (20.0)	8 (38.1)
Study terminated by Sponsor	0	0	2 (20.0)	2 (9.5)
Withdrawal of consent	1 (25.0)	0	1 (10.0)	2 (9.5)
Other	0	1 (14.3)	2 (20.0)	3 (14.3)
Primary reason for end of study				
Death	3 (75.0)	2 (28.6)	2 (20.0)	7 (33.3)
Non-compliance with study drug	0	1 (14.3)	0	1 (4.8)
Study terminated by Sponsor	0	2 (28.6)	5 (50.0)	7 (33.3)
Withdrawal of consent	1 (25.0)	0	0	1 (4.8)
Other	0	2 (28.6)	3 (30.0)	5 (23.8)

Source: Table [14.1-1](#)

10.2 Demographic and Baseline Characteristics

The majority of patients (16, 76.2%) were males. Age ranged from 27 to 93 years with a mean of 66.7 years. The majority of patients were not Hispanic or Latino (14, 66.7%) and White (17, 81.0%). Demographic and baseline characteristics are summarized in Table 14.1-4 and shown by patient in Listing 16.2-4.1.

Medical history is shown in Listing 16.2-4.2 and prior and concomitant medications in Listing 16.2-4.9.1.

12 SAFETY EVALUATION

12.1 Extent of Exposure

Exposure to study treatment overall and by cycle is summarized in Table 14.1-8. Four patients received 800 mg NOX66 for a mean of 25.3 days (range 2 to 62) and a mean dose of 13,200 mg (range 1,200 to 28,000). Seven patients received 1200 mg NOX66 for a mean of 123.0 days (range 3 to 418) and a mean dose of 76,114 mg (range 2,400 to 235,200). Ten patients received 1600 mg NOX66 for a mean of 87.0 days (range 12 to 265) and a mean dose of 65,760 mg (range 15,600 to 217,600).

Overall, the most frequent locations of radiation were liver (5, 23.8%) and bone (3, 14.3%); the lesions were most often pre-identified (13, 61.9%), the most frequent radiation technique was intensity-modulated radiation therapy (12, 57.1%), and the most frequent regimen was 20 Gy as 5 fractions (15, 71.4%). The mean total radiation dose was 230.8 Gy (range 8 to 1000).

Treatment exposure is shown for NOX66 in Listing 16.2-5.1.1 and EBRT administration in Listing 16.2-5.1.2.

12.2 Adverse Events

12.2.1 Display of Adverse Events

An overview of AEs is provided in Table 14.3-1.1 and TEAEs are summarized by system organ class and preferred term for all TEAEs in Table 14.3-1.3, for TEAEs related to NOX66 in Table 14.3-1.6, and by maximum severity in Table 14.3-1.13.

Table 2. Overview of Adverse Events

	NOX66 Dose Escalation			Total (N = 21) n (%) / E
	800 mg (N = 4) n (%) / E	1200 mg (N = 7) n (%) / E	1600 mg (N = 10) n (%) / E	
Number of patients with ≥ 1 :				
AE	4 (100) / 24	7 (100) / 64	9 (90.0) / 142	20 (95.2) / 230
TEAE	4 (100) / 23	7 (100) / 62	9 (90.0) / 133	20 (95.2) / 218
DLT	0	0	0	0
TEAE by NCI CTCAE toxicity:				
Grade 1	3 (75.0) / 14	1 (14.3) / 34	1 (10.0) / 89	5 (23.8) / 137
Grade 2	0 / 6	1 (14.3) / 20	3 (30.0) / 32	4 (19.0) / 58
Grade 3	0 / 2	4 (57.1) / 7	4 (40.0) / 11	8 (38.1) / 20
Grade 4	1 (25.0) / 1	0 / 0	1 (10.0) / 1	2 (9.5) / 2
Grade 5	0 / 0	1 (14.3) / 1	0 / 0	1 (4.8) / 1
TEAE by relationship to NOX66:				
Related (possibly related or related to NOX66)	4 (100) / 7	4 (57.1) / 9	6 (60.0) / 47	14 (66.7) / 63
TEAE by relationship to EBRT:				
Possibly related	1 (25.0) / 1	2 (28.6) / 2	3 (30.0) / 8	5 (23.8) / 10
Related	0 / 0	2 (28.6) / 4	2 (20.0) / 6	4 (19.0) / 10
SAE	1 (25.0) / 2	3 (42.9) / 4	5 (50.0) / 8	9 (42.9) / 14
TESAE	1 (25.0) / 2	3 (42.9) / 4	4 (40.0) / 7	8 (38.1) / 13
Study drug related TESAE	1 (25.0) / 1	0 / 0	2 (20.0) / 2	3 (14.3) / 3
TESAE leading to drug withdrawal	0 / 0	1 (14.3) / 1	0 / 0	1 (4.8) / 1
TESAE leading to drug interruption	1 (25.0) / 2	1 (14.3) / 2	3 (30.0) / 3	5 (23.8) / 7
TEAE leading to fatal outcome	0 / 0	1 (14.3) / 1	0 / 0	1 (4.8) / 1

AE = adverse event; DLT = dose-limiting toxicity; NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events; SAE = serious adverse event; TEAE = treatment-emergent adverse event

Source: Table 14.3-1.1

Table 3. Treatment-Emergent Adverse Events Reported for 2 or More Patients

System Organ Class Preferred Term	NOX66 Dose Escalation			Total (N = 21) n (%) / E
	800 mg (N = 4) n (%) / E	1200 mg (N = 7) n (%) / E	1600 mg (N = 10) n (%) / E	
Investigations				
Lymphocyte count decreased	0 / 0	2 (28.6) / 7	5 (50.0) / 11	7 (33.3) / 18
Blood alkaline phosphatase increased	0 / 0	0 / 0	2 (20.0) / 4	2 (9.5) / 4

System Organ Class Preferred Term	NOX66 Dose Escalation			Total (N = 21) n (%) / E
	800 mg (N = 4) n (%) / E	1200 mg (N = 7) n (%) / E	1600 mg (N = 10) n (%) / E	
Blood creatinine increased	0 / 0	1 (14.3) / 1	1 (10.0) / 1	2 (9.5) / 2
Neutrophil count decreased	1 (25.0) / 1	1 (14.3) / 6	0 / 0	2 (9.5) / 7
SARS-COV-2 test positive	0 / 0	1 (14.3) / 1	1 (10.0) / 1	2 (9.5) / 2
White blood cell count decreased	1 (25.0) / 1	1 (14.3) / 5	0 / 0	2 (9.5) / 6
Metabolism and nutrition disorders				
Hypercalcaemia	0 / 0	3 (42.9) / 5	1 (10.0) / 1	4 (19.0) / 6
Dehydration	1 (25.0) / 3	2 (28.6) / 2	0 / 0	3 (14.3) / 5
Hyperglycaemia	0 / 0	0 / 0	2 (20.0) / 5	2 (9.5) / 5
Hyperkalaemia	1 (25.0) / 1	1 (14.3) / 1	0 / 0	2 (9.5) / 2
Hypoalbuminaemia	0 / 0	1 (14.3) / 1	1 (10.0) / 1	2 (9.5) / 2
Gastrointestinal disorders				
Nausea	2 (50.0) / 2	0 / 0	4 (40.0) / 5	6 (28.6) / 7
Diarrhoea	1 (25.0) / 1	1 (14.3) / 1	2 (20.0) / 2	4 (19.0) / 4
Anorectal discomfort	1 (25.0) / 1	0 / 0	1 (10.0) / 1	2 (9.5) / 2
Proctitis	1 (25.0) / 1	0 / 0	1 (10.0) / 2	2 (9.5) / 3
Rectal haemorrhage	0 / 0	0 / 0	2 (20.0) / 4	2 (9.5) / 4
Musculoskeletal and connective tissue disorders				
Back pain	2 (50.0) / 2	2 (28.6) / 2	3 (30.0) / 4	7 (33.3) / 8
Nervous system disorders				
Dizziness	0 / 0	0 / 0	2 (20.0) / 3	2 (9.5) / 3
Headache	1 (25.0) / 1	0 / 0	1 (10.0) / 1	2 (9.5) / 2
Respiratory, thoracic and mediastinal disorders				
Dyspnoea	0 / 0	0 / 0	3 (30.0) / 4	3 (14.3) / 4
General disorders and administration site conditions				
Fatigue	1 (25.0) / 1	2 (28.6) / 2	2 (20.0) / 3	5 (23.8) / 6
Blood and lymphatic system disorders				
Lymphopenia	2 (50.0) / 2	1 (14.3) / 6	1 (10.0) / 2	4 (19.0) / 10
Anaemia	1 (25.0) / 2	0 / 0	1 (10.0) / 2	2 (9.5) / 6
Psychiatric disorders				
Insomnia	0 / 0	0 / 0	2 (20.0) / 2	2 (9.5) / 2
Renal and urinary disorders				
Proteinuria	0 / 0	0 / 0	2 (20.0) / 4	2 (9.5) / 4

Source: Table 14.3-1.3

Table 4. Treatment-Emergent Adverse Events Related to NOX66 Reported for 2 or More Patients

System Organ Class Preferred Term	NOX66 Dose Escalation			Total (N = 21) n (%) / E
	800 mg (N = 4) n (%) / E	1200 mg (N = 7) n (%) / E	1600 mg (N = 10) n (%) / E	
Gastrointestinal disorders				
Diarrhoea	1 (25.0) / 1	1 (14.3) / 1	1 (10.0) / 1	3 (14.3) / 3
Anorectal discomfort	1 (25.0) / 1	0 / 0	1 (10.0) / 1	2 (9.5) / 2
Nausea	1 (25.0) / 1	0 / 0	1 (10.0) / 2	2 (9.5) / 3
Proctitis	1 (25.0) / 1	0 / 0	1 (10.0) / 2	2 (9.5) / 3
Investigations				
Lymphocyte count decreased	0 / 0	2 (28.6) / 3	2 (20.0) / 5	4 (19.0) / 8
Blood and lymphatic system disorders				
Anaemia	1 (25.0) / 1	0 / 0	1 (10.0) / 4	2 (9.5) / 5

Source: Table 14.3-1.6

12.2.2 Analysis of Adverse Events

No DLTs occurred during the study (Listing 16.2-9.1)

All patients except 1 experienced TEAEs during the study with 218 TEAEs reported (Table 2). The TEAEs reported for 2 or more patients are summarized in Table 3. The most frequently reported TEAEs were lymphocyte count decreased and back pain (each 7 patients) and nausea (6 patients). TEAEs generally showed no apparent dose relationship, except for lymphocyte count decreased, which was reported for 0%, 28.6%, and 50.0% of patients in the 800, 1200, and 1600 mg cohorts, respectively.

The TEAEs considered related to NOX66 that were reported most frequently were lymphocyte count decreased (4 patients) and diarrhea (3 patients; Table 14.3-1.6).

Of the 218 TEAEs, most were mild (137) or moderate (58). Twenty events were reported as severe, 2 as life-threatening, and 1 as fatal (Table 14.3-1.13).

12.2.3 Listing of Adverse Events by Patient

All AEs are shown by patient in Listing 16.2-9.2.

12.3 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

12.3.1 Listing of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

Deaths are shown in Listing [16.2-9.7](#). One death was due to the TESA of acute respiratory failure and the other deaths were due to disease progression.

Eight patients experienced a total of 13 treatment-emergent serious adverse event (TESAEs) (Listing [16.2-9.3](#)). These included Patient 200105 (NOX66 1200 mg) who discontinued study drug and the study due to a fatal TESAE of acute respiratory failure (Listings [16.2-9.4](#), [16.2-9.5](#), and [16.2-9.6](#)).

Two other patients discontinued the study due to TEAEs (Listing [16.2-9.6](#)). Patient 300201 (1600 mg) discontinued the study due to the TESAE of general physical health deterioration (see below). Patient 300202, a 57-year-old white male, was treated with 1600 mg NOX66 for Cycle 1 on Study Days 1 to 14 (07 to 20Dec2022) and received EBRT to the paravertebral terime on Study Days 2 to 6 and cervical I-II vertebra on Study Days 2 to 8. He also received NOX66 for Cycle 2 on Study Days 22 to 28 (28Dec2022 to 03Jan2023). The patient experienced a TEAE of abdominal distension starting on Study Day 40 (15Jan2023) that was considered Grade 1, possibly related to NOX66, not related to EBRT, was ongoing, and led to treatment discontinuation.

One additional patient experienced an SAE. Patient 200110, a 67-year-old white male, was treated with 1600 mg NOX66 for Cycle 1 on Study Days 1 to 14 (16 to 29Mar2023) and received EBRT to the pelvis on Study Day 2. He experienced an SAE of abnormal diagnostic imaging cord compression (verbatim; preferred term uncoded; serious criterion hospitalization) starting on Study Day 63 (17May2023). The event was considered Grade 3, unrelated to NOX66 and EBRT, and was ongoing (Listing [16.2-9.3](#)). The patient discontinued the study on 28May2023 due to study termination by the Sponsor.

12.3.2 Narratives of Deaths, Other Serious Adverse Events, and Certain Other Significant Adverse Events

The CRFs for the 8 patients who experienced TESAEs are provided in Appendix [16.3.1](#).

Patient 200105

This 74-year-old white male was treated with 1200 mg NOX66 for Cycle 1 on Study Days 1 to 8 (07 to 14Jul2022) and received EBRT to the liver on Study Days 2 to 8 (08 to 14Jul2022). He experienced a TESAE of acute respiratory failure starting on Study Day 8 (14Jul2022) and died due to the event on Study Day 19 (25Jul2022). The fatal event was considered not related to NOX66 or EBRT.

Patient 200204

This 60-year-old white female was treated with 800 mg NOX66 for Cycle 1 on Study Days 1 to 15 (01 to 15Dec2021) and received EBRT to the lung on Study Days 2, 3, 6, 8, and 9. She experienced the 2 TESAEs shown below. The patient died on 26Jan2022 due to progressive disease.

SAE (Preferred Term)	Start – End Dates	NCI CTCAE Grade	Relationship	Serious Criteria	Outcome
Anemia ^a	21Dec2021 (SD21) – 24Dec2021 (SD24)	Grade 4	NOX66: possibly related EBRT: not related	Life-threatening, hospitalization	Resolved
Non-cardiac chest pain	26Dec2021 (SD28) – 30Dec2021 (SD30)	Grade 3	NOX66: not related EBRT: not related	Hospitalization	Resolved

SD = study day

a Worsening of a pre-existing condition

Source: Listing [16.2-9.3](#)

Patient 200207

This 52-year-old white male was treated with 1200 mg NOX66 for Cycle 1 on Study Days 1 to 3 (06 to 08Apr2022) and received EBRT to the pelvis (non-bone) on Study Days 6 and 7. He experienced the 2 TESAEs shown below. The patient discontinued study treatment with the last dose on 08Apr2022 and the study on 03May2022 due to non-compliance with the study drug.

SAE (Preferred Term)	Start – End Dates	NCI CTCAE Grade	Relationship	Serious Criteria	Outcome
Encephalopathy	09Apr2022 (SD4) – 10Apr2022 (SD5)	Grade 3	NOX66: unlikely related EBRT: not related	Hospitalization	Resolved
Failure to thrive	14Apr2022 (SD9) - 22Apr2022 (SD17)	Grade 3	NOX66: unlikely related EBRT: unlikely related	Hospitalization	Resolved

SD = study day

Source: Listing [16.2-9.3](#)

Patient 200211

This 63-year-old white female was treated with 1200 mg NOX66 for Cycle 1 on Study Days 1 to 14 (26May2022 to 08Jun2022) and received EBRT to the abdomen on Study Days 2, 6, 8, and 9. She experienced a TESA of pleural effusion (serious criterion hospitalization) starting on Study Day 10 (04Jun2022). The event was considered Grade 2, unlikely related to NOX66, and not related to EBRT. The patient died on 10Jun2022 due to progressive disease.

Patient 200107

This 75-year-old white male was treated with 1600 mg NOX66 for Cycle 1 on Study Days 1 to 9 (15 to 23Sep2022) and received EBRT to the femur on Study Day 2. Study drug administration was interrupted due to a TESA of diarrhea (serious criterion hospitalization) from Study Day 9 (23Sep2022) to Study Day 12 (26Sep2022). The event was considered Grade 3, possibly related to NOX66 and EBRT. The patient received NOX66 through Cycle 11 with the last dose on 08Mar2023 (Study Day 175). He discontinued the study on 18May2023 due to study termination by the Sponsor.

Patient 200212

This 93-year-old white male was treated with 1200 mg NOX66 for Cycle 1 on Study Days 1 to 12 (24Aug2022 to 04Sep2022, with some interruptions during the cycle) and received EBRT to the chest on Study Days 2, 3, 6, 7, and 8. He experienced the 3 TESAEs shown below. The patient died on 16Sep2022 due to progressive disease.

SAE (Preferred Term)	Start – End Dates	NCI CTCAE Grade	Relationship	Serious Criteria	Outcome
Pain in extremity [leg pain] ^a	17Aug2022 (SD4) – 28Aug2022 (SD5)	Grade 3	NOX66: not related EBRT: not related	Hospitalization	Resolved
Sinus tachycardia	04Sep2022 (SD12) - ongoing	Grade 3	NOX66: possibly related EBRT: possibly related	Hospitalization	Ongoing
Respiratory distress	08Sep2022 (SD16) - ongoing	Grade 4	NOX66: unlikely related EBRT: unlikely related	Life-threatening, hospitalization	Ongoing

SD = study day

a Worsening of a pre-existing condition

Source: Listing [16.2-9.3](#)

Patient 200213

This 71-year-old white male was treated with 1600 mg NOX66 for Cycle 1 on Study Days 1 to 14 (01 to 14Sep2022) and received EBRT to the lung on Study Days 2, 6, 7, 8, and 9. He received NOX66 through Cycle 7 with the last dose on 21Dec2022 (Study Day 112). He experienced a TESA of angina pectoris (serious criterion hospitalization) from Study Day 120 (29Dec2022) to Study Day 124 (02Jan2023). The event was considered Grade 3 and not related to NOX66 and EBRT. He discontinued study treatment due to progressive disease and discontinued the study on 06Apr2023 due to study termination by the Sponsor.

Patient 300201

This 68-year-old white male was treated with 1600 mg NOX66 for Cycle 1 on Study Days 1 to 14 (05 to 18Oct2022, with some interruptions during the cycle) and received EBRT to the mediastinum and left lung apex on Study Days 2 to 8 and to the left shoulder/chest on Study Days 92 to 98. He received NOX66 through Cycle 7 with the last dose on 14Jan2023 (Study

Day 112). He experienced the 2 TESAEs shown below. The patient discontinued study treatment due to the TESA of general physical health deterioration and died on 01Mar2023 due to progressive disease.

SAE (Preferred Term)	Start – End Dates	NCI CTCAE Grade	Relationship	Serious Criteria	Outcome
Confusional state	13Oct2022 (SD9) – 14Oct2022 (SD10)	Grade 3	NOX66: not related EBRT: not related	Hospitalization	Resolving
General physical health deterioration	01Feb2023 (SD120) – 02Feb2023 (SD121)	Grade 3	NOX66: not related EBRT: not related	Hospitalization	Resolved with sequelae

SD = study day

Source: Listing [16.2-9.3](#)

12.3.3 Analysis and Discussion of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

No TESA was reported for more than 1 patient (Table [14.3-2.2](#)). Three TESAEs were considered related to NOX66: anemia for Patient 200204 (800 mg), diarrhea for Patient 200107 (1600 mg), and sinus tachycardia for Patient 200212 (1600 mg) (Table [14.3-2.3](#), Listing [16.2-9.3](#)).

12.4 Clinical Laboratory Evaluations

Laboratory-related TEAEs that were reported as related to study drug for more than 1 patient were lymphocyte count decreased (4 patients) and anemia (2 patients) (Table [14.3-1.6](#)).

Hematology parameters are summarized by treatment group and timepoint in Table [14.3-3.1](#) and are shown by patient in Listing [16.2-10.1](#).

Chemistry parameters are summarized by treatment group and timepoint in Table [14.3-3.2](#) and are shown by patient in Listing [16.2-10.2](#).

Coagulation parameters are summarized by treatment group and timepoint in Table [14.3-3.3](#) and are shown by patient in Listing [16.2-10.3](#).

Urinalysis parameters (dipstick) are summarized by treatment group in Table [14.3-3.4.1](#) and are shown by patient in Listings [16.2-10.4.1](#) (dipstick) and [16.2-10.4.2](#) (microscopic).

Testosterone is summarized by treatment group and timepoint in Table [14.3-3.5](#) and are shown by patient in Listing [16.2-10.5](#).

No positive pregnancy test results were reported during the study (Listing [16.2-10.6](#)).

Results for PSA, serology, FSH, SARS-CoV-2, and non-protocol laboratory assessments are shown in Listings [16.2-10.7](#), [16.2-10.8](#), [16.2-10.9](#), [16.2-10.10](#), and [16.2-11.5](#).

12.5 Vital Signs, Physical Findings, and Other Observations Related to Safety

Vital signs are summarized by treatment group and timepoint in Table 14.3-4.1 and are shown by patient in Listing 16.2-11.1.

The 12-lead ECG parameters are summarized by treatment group and timepoint in Table 14.3-4.3.1 and are shown by patient in Listing 16.2-11.3. Three patients had findings at a single timepoint that were reported as abnormal and clinically significant (Tables 14.3-4.3.2).

- Patient 200106 (1600 mg) had results pre-dose at Cycle 17 Day 1 of ECG mean heart rate of 69 beats/min, PR interval of 182 msec, QRS duration of 94 msec, QT interval of 388 msec, and QTc interval of 406.3 msec. All other results for the patient were reported as normal or abnormal and not clinically significant.
- Patient 200107 (1600 mg) had results pre-dose at End of Treatment (following 13 cycles) of ECG mean heart rate of 55 beats/min, PR interval of 262 msec, QRS duration of 133 msec, QT interval of 452 msec, and QTc interval of 439.2 msec. All other results for the patient were reported as abnormal and not clinically significant.
- Patient 200213 (1600 mg) had results pre-dose at Cycle 9 Day 1 of ECG mean heart rate of 92 beats/min, PR interval of 156 msec, QRS duration of 68 msec, QT interval of 364 msec, and QTc interval of 419.1 msec. All other results for the patient were reported as abnormal and not clinically significant.

Results are shown in Listing 16.2-11.2 for physical examination findings and Listing 16.2-11.4 for ECOG performance status.

13 DISCUSSION AND OVERALL CONCLUSIONS

In Part 1 of this open-label dose escalation study, NOX66 was shown to be safe and well-tolerated at doses of 800, 1200, and 1600 mg administered with EBRT in adult patients with a solid tumor. Dose escalation progressed through the first 3 planned dose levels before the Sponsor decided to terminate the study early for business reasons.

**14 TABLES, FIGURES, AND GRAPHS REFERRED TO BUT NOT INLCUED
IN THE TEXT**

Table 14.1-1
Patient Disposition
(Enrolled Set)

	Dose Escalation			Total
	800 mg	1200 mg	1600 mg	
	N=4 n (%)	N=7 n (%)	N=10 n (%)	N=21 n (%)
Screened				30
Screen failures				9
Treated	4	7	10	21
Primary Reason for End of Treatment				
New Anti-Cancer Treatment	0	0	0	0
Unacceptable Toxicity	0	0	1 (10.0)	1 (4.8)
Adverse Event	0	0	1 (10.0)	1 (4.8)
Death	0	2 (28.6)	1 (10.0)	3 (14.3)
Investigator Discretion	0	0	0	0
Lost to Follow-up	0	0	0	0
Non-Compliance with Study Drug	0	1 (14.3)	0	1 (4.8)
Pregnancy	0	0	0	0
Physician Decision	0	0	0	0
Progressive Disease	3 (75.0)	3 (42.9)	2 (20.0)	8 (38.1)
Protocol Violation	0	0	0	0
Study Terminated by Sponsor	0	0	2 (20.0)	2 (9.5)
Trial Site Terminated by Sponsor	0	0	0	0
Withdrawal of Consent	1 (25.0)	0	1 (10.0)	2 (9.5)
Other	0	1 (14.3)	2 (20.0)	3 (14.3)

N = number of patients in the analysis set; n = number of patients in the specified category; Percentage (%) = $n/N * 100$.

(1) Percentages were based on the number of treated patients (Safety Set).

(2) Treated subjects are based on actual treatment rather than planned/assigned treatment.

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Table 14.1-1
Patient Disposition
(Enrolled Set)

	Dose Escalation			Total
	800 mg	1200 mg	1600 mg	
	N=4 n (%)	N=7 n (%)	N=10 n (%)	N=21 n (%)
Primary Reason for End of Treatment Related to COVID-19	0	0	0	0
Primary Reason for End of Study				
Adverse Event	0	0	0	0
Death	3 (75.0)	2 (28.6)	2 (20.0)	7 (33.3)
End of Follow-up Period	0	0	0	0
Investigator Discretion	0	0	0	0
Lost to Follow-up	0	0	0	0
Non-Compliance with Study Drug	0	1 (14.3)	0	1 (4.8)
Pregnancy	0	0	0	0
Progressive Disease	0	0	0	0
Protocol Violation	0	0	0	0
Study Terminated by Sponsor	0	2 (28.6)	5 (50.0)	7 (33.3)
Trial Site Terminated by Sponsor	0	0	0	0
Withdrawal of Consent	1 (25.0)	0	0	1 (4.8)
Other	0	2 (28.6)	3 (30.0)	5 (23.8)

N = number of patients in the analysis set; n = number of patients in the specified category; Percentage (%) = $n/N * 100$.

(1) Percentages were based on the number of treated patients (Safety Set).

(2) Treated subjects are based on actual treatment rather than planned/assigned treatment.

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Table 14.1-4
Demography and Other Baseline Characteristics
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Age at informed consent (years)				
Nx	4	7	10	21
Mean	69.5	67.7	64.9	66.7
SD	8.23	12.57	18.05	14.41
Median	69.0	73.0	67.5	68.0
Q1, Q3	64.0, 75.0	52.0, 79.0	57.0, 75.0	60.0, 75.0
Min, Max	60, 80	51, 82	27, 93	27, 93
Sex n(%)				
Female	3 (75.0)	1 (14.3)	1 (10.0)	5 (23.8)
Male	1 (25.0)	6 (85.7)	9 (90.0)	16 (76.2)
Is the female patient of childbearing potential n(%)				
Yes	0	0	1 (100)	1 (20.0)
No	3 (100)	1 (100)	0	4 (80.0)
Is the female patient post-menopausal n(%)				
Yes	3 (100)	1 (100)	0	4 (80.0)
No	0	0	0	0

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$.

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Table 14.1-4
Demography and Other Baseline Characteristics
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Ethnicity n(%)				
Hispanic or Latino	2 (50.0)	2 (28.6)	3 (30.0)	7 (33.3)
Not Hispanic or Latino	2 (50.0)	5 (71.4)	7 (70.0)	14 (66.7)
Not Stated	0	0	0	0
Unknown	0	0	0	0
Tobacco or smoking history n(%)				
Never	3 (75.0)	4 (57.1)	7 (70.0)	14 (66.7)
Former	0	2 (28.6)	2 (20.0)	4 (19.0)
Current	0	0	1 (10.0)	1 (4.8)
Unknown	1 (25.0)	1 (14.3)	0	2 (9.5)
Alcohol consumption history n(%)				
Never	3 (75.0)	1 (14.3)	3 (30.0)	7 (33.3)
Former	0	3 (42.9)	3 (30.0)	6 (28.6)
Current	0	2 (28.6)	4 (40.0)	6 (28.6)
Unknown	1 (25.0)	1 (14.3)	0	2 (9.5)

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$.

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Table 14.1-4
Demography and Other Baseline Characteristics
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Race n(%)				
American Indian or Alaska Native	0	0	1 (10.0)	1 (4.8)
Asian	0	0	0	0
Black or African American	1 (25.0)	2 (28.6)	0	3 (14.3)
Native Hawaiian or Other Pacific Islander	0	0	0	0
White	3 (75.0)	5 (71.4)	9 (90.0)	17 (81.0)

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Treatment duration (Days) (1)				
Nx	4	7	10	21
Mean	25.3	123.0	87.0	87.2
SD	25.86	148.28	83.76	105.21
Median	18.5	84.0	69.0	37.0
Q1, Q3	8.5, 42.0	8.0, 168.0	14.0, 112.0	14.0, 112.0
Min, Max	2, 62	3, 418	12, 265	2, 418
Dose of suppositories administered (mg)				
Total:				
Nx	4	7	10	21
Mean	33.0	126.9	164.4	126.9
SD	27.65	137.62	169.52	145.58
Median	29.5	98.0	78.0	70.0
Q1, Q3	16.0, 50.0	14.0, 182.0	56.0, 252.0	30.0, 170.0
Min, Max	3, 70	4, 392	39, 544	3, 544

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Cycle 1 Day 1:				
Nx	4	7	10	21
Mean	22.3	22.6	46.5	33.9
SD	12.87	9.71	11.84	16.36
Median	28.0	28.0	54.0	28.0
Q1, Q3	15.5, 29.0	14.0, 28.0	36.0, 56.0	28.0, 52.0
Min, Max	3, 30	4, 28	28, 56	3, 56
Cycle 2 Day 1:				
Nx	2	4	7	13
Mean	14.5	11.0	31.1	22.4
SD	19.09	6.00	21.04	18.95
Median	14.5	14.0	28.0	14.0
Q1, Q3	1.0, 28.0	8.0, 14.0	12.0, 56.0	12.0, 28.0
Min, Max	1, 28	2, 14	10, 64	1, 64

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Cycle 3 Day 1:				
Nx	1	4	5	10
Mean	14.0	28.0	38.6	31.9
SD	NC	0.00	24.04	18.00
Median	14.0	28.0	52.0	28.0
Q1, Q3	14.0, 14.0	28.0, 28.0	28.0, 56.0	28.0, 52.0
Min, Max	14, 14	28, 28	1, 56	1, 56
Cycle 5 Day 1:				
Nx	0	4	5	9
Mean	NC	28.0	42.2	35.9
SD	NC	0.00	23.96	18.52
Median	NC	28.0	56.0	28.0
Q1, Q3	NC, NC	28.0, 28.0	28.0, 56.0	28.0, 56.0
Min, Max	NC, NC	28, 28	7, 64	7, 64

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Cycle 7 Day 1:				
Nx	0	3	5	8
Mean	NC	28.0	37.8	34.1
SD	NC	0.00	23.54	18.50
Median	NC	28.0	48.0	28.0
Q1, Q3	NC, NC	28.0, 28.0	28.0, 56.0	28.0, 52.0
Min, Max	NC, NC	28, 28	1, 56	1, 56
Cycle 9 Day 1:				
Nx	0	3	3	6
Mean	NC	28.0	29.3	28.7
SD	NC	0.00	25.72	16.28
Median	NC	28.0	40.0	28.0
Q1, Q3	NC, NC	28.0, 28.0	0.0, 48.0	28.0, 40.0
Min, Max	NC, NC	28, 28	0, 48	0, 48

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Cycle 11 Day 1:				
Nx	0	3	2	5
Mean	NC	28.0	56.0	39.2
SD	NC	0.00	0.00	15.34
Median	NC	28.0	56.0	28.0
Q1, Q3	NC, NC	28.0, 28.0	56.0, 56.0	28.0, 56.0
Min, Max	NC, NC	28, 28	56, 56	28, 56
Cycle 13 Day 1:				
Nx	0	1	1	2
Mean	NC	28.0	56.0	42.0
SD	NC	NC	NC	19.80
Median	NC	28.0	56.0	42.0
Q1, Q3	NC, NC	28.0, 28.0	56.0, 56.0	28.0, 56.0
Min, Max	NC, NC	28, 28	56, 56	28, 56

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Cycle 15 Day 1:				
Nx	0	1	1	2
Mean	NC	28.0	56.0	42.0
SD	NC	NC	NC	19.80
Median	NC	28.0	56.0	42.0
Q1, Q3	NC, NC	28.0, 28.0	56.0, 56.0	28.0, 56.0
Min, Max	NC, NC	28, 28	56, 56	28, 56
Cycle 17 Day 1:				
Nx	0	1	1	2
Mean	NC	28.0	56.0	42.0
SD	NC	NC	NC	19.80
Median	NC	28.0	56.0	42.0
Q1, Q3	NC, NC	28.0, 28.0	56.0, 56.0	28.0, 56.0
Min, Max	NC, NC	28, 28	56, 56	28, 56

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Cycle 19 Day 1:				
Nx	0	1	0	1
Mean	NC	28.0	NC	28.0
SD	NC	NC	NC	NC
Median	NC	28.0	NC	28.0
Q1, Q3	NC, NC	28.0, 28.0	NC, NC	28.0, 28.0
Min, Max	NC, NC	28, 28	NC, NC	28, 28
Cycle 21 Day 1:				
Nx	0	1	0	1
Mean	NC	28.0	NC	28.0
SD	NC	NC	NC	NC
Median	NC	28.0	NC	28.0
Q1, Q3	NC, NC	28.0, 28.0	NC, NC	28.0, 28.0
Min, Max	NC, NC	28, 28	NC, NC	28, 28

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Cycle 23 Day 1:				
Nx	0	1	0	1
Mean	NC	28.0	NC	28.0
SD	NC	NC	NC	NC
Median	NC	28.0	NC	28.0
Q1, Q3	NC, NC	28.0, 28.0	NC, NC	28.0, 28.0
Min, Max	NC, NC	28, 28	NC, NC	28, 28
Cycle 25 Day 1:				
Nx	0	1	0	1
Mean	NC	42.0	NC	42.0
SD	NC	NC	NC	NC
Median	NC	42.0	NC	42.0
Q1, Q3	NC, NC	42.0, 42.0	NC, NC	42.0, 42.0
Min, Max	NC, NC	42, 42	NC, NC	42, 42
Subjects with a dose modification n(%)	1 (25.0)	4 (57.1)	7 (70.0)	12 (57.1)

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Type of modification n(%):				
Dose Reduced	0	0	2 (20.0)	2 (9.5)
Dose Discontinued	1 (25.0)	1 (14.3)	1 (10.0)	3 (14.3)
Drug Interrupted	0	3 (42.9)	6 (60.0)	9 (42.9)
Reason for modification n(%):				
Adverse Event	0	3 (42.9)	5 (50.0)	8 (38.1)
Subject Non-Compliant	0	1 (14.3)	0	1 (4.8)
Investigator Discretion	0	0	0	0
Subject Error	0	0	0	0
Dosing Error	0	0	0	0
Other	1 (25.0)	0	3 (30.0)	4 (19.0)
Number with radiotherapy n(%)	4 (100)	7 (100)	10 (100)	21 (100)

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N \times 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Location of radiation n(%):				
Abdomen	0	1 (14.3)	0	1 (4.8)
Bone	0	3 (42.9)	0	3 (14.3)
Brain	0	0	0	0
Chest	0	0	1 (10.0)	1 (4.8)
Head and Neck	0	0	0	0
Liver	0	1 (14.3)	0	1 (4.8)
Lung	3 (75.0)	0	2 (20.0)	5 (23.8)
Lymph Node	0	0	1 (10.0)	1 (4.8)
Pelvis (non-bone)	0	1 (14.3)	0	1 (4.8)
Prostate Gland	0	0	0	0
Skin	0	0	0	0
Spine	1 (25.0)	0	1 (10.0)	2 (9.5)
Other	0	1 (14.3)	5 (50.0)	6 (28.6)
Laterality n(%):				
Left	2 (50.0)	1 (14.3)	3 (30.0)	6 (28.6)
Right	1 (25.0)	2 (28.6)	3 (30.0)	6 (28.6)
Not Applicable	1 (25.0)	4 (57.1)	5 (50.0)	10 (47.6)

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Pre-identified lesion n(%):				
No	1 (25.0)	3 (42.9)	5 (50.0)	9 (42.9)
Yes	3 (75.0)	4 (57.1)	6 (60.0)	13 (61.9)
Radiation technique used n(%):				
IMRT	4 (100)	4 (57.1)	4 (40.0)	12 (57.1)
VMAT	0	0	3 (30.0)	3 (14.3)
Other	0	3 (42.9)	4 (40.0)	7 (33.3)
Regimen n(%):				
8 Gray (Gy) as a single fraction	0	1 (14.3)	1 (10.0)	2 (9.5)
20 Gray (Gy) as 5 fractions	4 (100)	3 (42.9)	8 (80.0)	15 (71.4)
25 Gray (Gy) as 5 fractions	0	4 (57.1)	2 (20.0)	6 (28.6)
Other	0	0	1 (10.0)	1 (4.8)

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.1-8
Extent of Exposure
(Safety Set)

	Dose Escalation			Total
	800 mg N=4	1200 mg N=7	1600 mg N=10	N=21
Total dose (Gy):				
Nx	4	7	10	21
Mean	112.0	209.0	293.5	230.8
SD	192.08	243.39	365.54	297.31
Median	20.0	25.0	70.0	35.0
Q1, Q3	14.0, 210.0	10.0, 500.0	20.0, 500.0	20.0, 400.0
Min, Max	8, 400	8, 500	20, 1000	8, 1000
Number of fractions:				
Nx	4	7	10	21
Mean	4.3	4.9	5.7	5.1
SD	1.50	4.85	3.37	3.58
Median	5.0	5.0	5.0	5.0
Q1, Q3	3.5, 5.0	1.0, 5.0	5.0, 10.0	2.0, 5.0
Min, Max	2, 5	1, 15	1, 10	1, 15

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3.

N = number of patients in the analysis set; n = number of patients in the specified category; Nx = number of patients with non-missing values; Percentage (%) = $n/N * 100$. NC = Not Calculated.

(1) Treatment duration (in days) = date of last treatment - date of first treatment + 1.

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Table 14.3-1.1
Overview of Adverse Events
(Safety Set)

	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
With at least one:								
AE	4 (100.0)	24	7 (100.0)	64	9 (90.0)	142	20 (95.2)	230
TEAE	4 (100.0)	23	7 (100.0)	62	9 (90.0)	133	20 (95.2)	218
DLT	0	0	0	0	0	0	0	0
TEAE by Outcome:								
Fatal	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Not Recovered or Not Resolved	1 (25.0)	2	3 (42.9)	13	7 (70.0)	39	11 (52.4)	54
Recovered or Resolved	3 (75.0)	12	6 (85.7)	39	8 (80.0)	68	17 (81.0)	119
Recovered or Resolved with Sequelae	0	0	1 (14.3)	1	2 (20.0)	3	3 (14.3)	4
Recovering or Resolving	3 (75.0)	9	3 (42.9)	8	4 (40.0)	23	10 (47.6)	40
Unknown	0	0	0	0	0	0	0	0

AE = adverse event; TEAE = treatment-emergent adverse event; SAE = serious adverse event; TESAE = treatment-emergent serious event.
N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once even if reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

If a patient reports more than one AE the AE with the worst severity will be reported.

If severity or relatedness is missing then the worst case will be assumed; ie for severity the worst severity will be assumed and for causality it will be assumed that it is related to the treatment.

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Table 14.3-1.1
Overview of Adverse Events
(Safety Set)

	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
TEAE by NCI CTCAE Toxicity:								
Grade 1	3 (75.0)	14	1 (14.3)	34	1 (10.0)	89	5 (23.8)	137
Grade 2	0	6	1 (14.3)	20	3 (30.0)	32	4 (19.0)	58
Grade 3	0	2	4 (57.1)	7	4 (40.0)	11	8 (38.1)	20
Grade 4	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Grade 5	0	0	1 (14.3)	1	0	0	1 (4.8)	1
TEAE related to Study Treatment (possibly Related or Related) (NOX66)								
Related	4 (100.0)	7	4 (57.1)	9	6 (60.0)	47	14 (66.7)	63

AE = adverse event; TEAE = treatment-emergent adverse event; SAE = serious adverse event; TESAE = treatment-emergent serious event.
N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once even if reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

If a patient reports more than one AE the AE with the worst severity will be reported.

If severity or relatedness is missing then the worst case will be assumed; ie for severity the worst severity will be assumed and for causality it will be assumed that it is related to the treatment.

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Table 14.3-1.1
Overview of Adverse Events
(Safety Set)

	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
TEAE by Relationship to Study Treatment (NOX66):								
Not Related	4 (100.0)	16	7 (100.0)	38	9 (90.0)	76	20 (95.2)	130
Unlikely Related	0	0	3 (42.9)	15	3 (30.0)	10	6 (28.6)	25
Possibly Related	4 (100.0)	6	4 (57.1)	8	6 (60.0)	30	14 (66.7)	44
Related	1 (25.0)	1	1 (14.3)	1	2 (20.0)	17	4 (19.0)	19
TEAE by Relationship to EBRT Administration:								
Not Related	4 (100.0)	22	7 (100.0)	52	9 (90.0)	106	20 (95.2)	180
Unlikely Related	0	0	2 (28.6)	2	3 (30.0)	8	5 (23.8)	10
Possibly Related	1 (25.0)	1	2 (28.6)	4	5 (50.0)	13	8 (38.1)	18
Related	0	0	2 (28.6)	4	2 (20.0)	6	4 (19.0)	10

AE = adverse event; TEAE = treatment-emergent adverse event; SAE = serious adverse event; TESAE = treatment-emergent serious event.
N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once even if reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

If a patient reports more than one AE the AE with the worst severity will be reported.

If severity or relatedness is missing then the worst case will be assumed; ie for severity the worst severity will be assumed and for causality it will be assumed that it is related to the treatment.

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Table 14.3-1.1
Overview of Adverse Events
(Safety Set)

	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
TEAE by Relationship to Study Procedure:								
No	4 (100.0)	23	7 (100.0)	61	9 (90.0)	118	20 (95.2)	202
Yes	0	0	1 (14.3)	1	2 (20.0)	15	3 (14.3)	16
TEAE by Action Taken with Study Treatment:								
Dose Not Changed	4 (100.0)	20	6 (85.7)	56	9 (90.0)	90	19 (90.5)	166
Dose Reduced	0	0	0	0	2 (20.0)	2	2 (9.5)	2
Drug Interrupted	1 (25.0)	2	2 (28.6)	4	4 (40.0)	17	7 (33.3)	23
Drug Withdrawn	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Not Applicable	1 (25.0)	1	1 (14.3)	1	4 (40.0)	24	6 (28.6)	26
Unknown	0	0	0	0	0	0	0	0

AE = adverse event; TEAE = treatment-emergent adverse event; SAE = serious adverse event; TESAE = treatment-emergent serious event.
N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = n/N * 100.

For the summarization of number of patients (n), a patient is counted only once even if reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

If a patient reports more than one AE the AE with the worst severity will be reported.

If severity or relatedness is missing then the worst case will be assumed; ie for severity the worst severity will be assumed and for causality it will be assumed that it is related to the treatment.

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Table 14.3-1.1
Overview of Adverse Events
(Safety Set)

	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
TEAE by Other Action Taken:								
None	4 (100.0)	14	6 (85.7)	53	9 (90.0)	100	19 (90.5)	167
Hospitalization or prolongation of hospitalization	1 (25.0)	2	3 (42.9)	3	4 (40.0)	5	8 (38.1)	10
Concomitant medication	2 (50.0)	6	4 (57.1)	5	8 (80.0)	19	14 (66.7)	30
Therapeutic or diagnostic procedure	1 (25.0)	1	1 (14.3)	1	2 (20.0)	9	4 (19.0)	11
Other	0	0	0	0	0	0	0	0
TEAE by Pattern:								
Intermittent	2 (50.0)	11	5 (71.4)	15	7 (70.0)	31	14 (66.7)	57
Continue	4 (100.0)	12	7 (100.0)	47	9 (90.0)	102	20 (95.2)	161

AE = adverse event; TEAE = treatment-emergent adverse event; SAE = serious adverse event; TESAE = treatment-emergent serious event.
N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once even if reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

If a patient reports more than one AE the AE with the worst severity will be reported.

If severity or relatedness is missing then the worst case will be assumed; ie for severity the worst severity will be assumed and for causality it will be assumed that it is related to the treatment.

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Table 14.3-1.1
Overview of Adverse Events
(Safety Set)

	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
SAE	1 (25.0)	2	3 (42.9)	4	5 (50.0)	8	9 (42.9)	14
TESAE	1 (25.0)	2	3 (42.9)	4	4 (40.0)	7	8 (38.1)	13
Study drug related SAE	1 (25.0)	1	0	0	2 (20.0)	2	3 (14.3)	3
Study drug related TESAE	1 (25.0)	1	0	0	2 (20.0)	2	3 (14.3)	3
TESAE leading to drug withdrawal	0	0	1 (14.3)	1	0	0	1 (4.8)	1
TESAE leading to drug interruption	1 (25.0)	2	1 (14.3)	2	3 (30.0)	3	5 (23.8)	7
TESAE leading to fatal outcome	0	0	1 (14.3)	1	0	0	1 (4.8)	1

AE = adverse event; TEAE = treatment-emergent adverse event; SAE = serious adverse event; TESAE = treatment-emergent serious event.
N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once even if reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

If a patient reports more than one AE the AE with the worst severity will be reported.

If severity or relatedness is missing then the worst case will be assumed; ie for severity the worst severity will be assumed and for causality it will be assumed that it is related to the treatment.

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Table 14.3-1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Patients with at least one TEAE	4 (100.0)	23	7 (100.0)	62	9 (90.0)	133	20 (95.2)	218
Investigations	1 (25.0)	2	4 (57.1)	22	8 (80.0)	25	13 (61.9)	49
Lymphocyte count decreased	0	0	2 (28.6)	7	5 (50.0)	11	7 (33.3)	18
Blood alkaline phosphatase increased	0	0	0	0	2 (20.0)	4	2 (9.5)	4
Blood creatinine increased	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
Neutrophil count decreased	1 (25.0)	1	1 (14.3)	6	0	0	2 (9.5)	7
SARS-CoV-2 test positive	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
White blood cell count decreased	1 (25.0)	1	1 (14.3)	5	0	0	2 (9.5)	6
Alanine aminotransferase increased	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Blood bicarbonate decreased	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Blood phosphorus decreased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Blood thyroid stimulating hormone increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Blood urea increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Brain natriuretic peptide increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Electrocardiogram ST segment elevation	0	0	0	0	1 (10.0)	1	1 (4.8)	1

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

/projects/noxop254919/stats/primary/prog/tables/t_teae.sas/04JUL2023/01:33

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Table 14.3-1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Gamma-glutamyltransferase increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Troponin increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Weight decreased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Metabolism and nutrition disorders	2 (50.0)	4	5 (71.4)	12	6 (60.0)	10	13 (61.9)	26
Hypercalcaemia	0	0	3 (42.9)	5	1 (10.0)	1	4 (19.0)	6
Dehydration	1 (25.0)	3	2 (28.6)	2	0	0	3 (14.3)	5
Hyperglycaemia	0	0	0	0	2 (20.0)	5	2 (9.5)	5
Hyperkalaemia	1 (25.0)	1	1 (14.3)	1	0	0	2 (9.5)	2
Hypoalbuminaemia	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
Decreased appetite	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Failure to thrive	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Hypokalaemia	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Hyponatraemia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Hypophagia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Hypophosphataemia	0	0	1 (14.3)	1	0	0	1 (4.8)	1

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Gastrointestinal disorders	3 (75.0)	5	1 (14.3)	2	7 (70.0)	29	11 (52.4)	36
Nausea	2 (50.0)	2	0	0	4 (40.0)	5	6 (28.6)	7
Diarrhoea	1 (25.0)	1	1 (14.3)	1	2 (20.0)	2	4 (19.0)	4
Anorectal discomfort	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Proctitis	1 (25.0)	1	0	0	1 (10.0)	2	2 (9.5)	3
Rectal haemorrhage	0	0	0	0	2 (20.0)	4	2 (9.5)	4
Abdominal distension	0	0	0	0	1 (10.0)	3	1 (4.8)	3
Anal pruritus	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Anal rash	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Constipation	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Dry mouth	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Dysphagia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Gastritis	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Hiatus hernia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Proctalgia	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Vomiting	0	0	0	0	1 (10.0)	3	1 (4.8)	3

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Musculoskeletal and connective tissue disorders	2 (50.0)	2	2 (28.6)	5	5 (50.0)	8	9 (42.9)	15
Back pain	2 (50.0)	2	2 (28.6)	2	3 (30.0)	4	7 (33.3)	8
Arthralgia	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Intervertebral disc protrusion	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Muscular weakness	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Musculoskeletal chest pain	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Myalgia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Osteoarthritis	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Pain in extremity	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Nervous system disorders	1 (25.0)	1	2 (28.6)	5	4 (40.0)	7	7 (33.3)	13
Dizziness	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Headache	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Ageusia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Burning sensation	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Encephalopathy	0	0	1 (14.3)	2	0	0	1 (4.8)	2

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Hypoaesthesia	0	0	1 (14.3)	2	0	0	1 (4.8)	2
Sensory loss	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Respiratory, thoracic and mediastinal disorders	0	0	2 (28.6)	2	5 (50.0)	11	7 (33.3)	13
Dyspnoea	0	0	0	0	3 (30.0)	4	3 (14.3)	4
Acute respiratory failure	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Asphyxia	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Cough	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Oropharyngeal pain	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Pleural effusion	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Respiratory distress	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Tachypnoea	0	0	0	0	1 (10.0)	1	1 (4.8)	1
General disorders and administration site conditions	1 (25.0)	2	2 (28.6)	2	3 (30.0)	8	6 (28.6)	12
Fatigue	1 (25.0)	1	2 (28.6)	2	2 (20.0)	3	5 (23.8)	6
Asthenia	0	0	0	0	1 (10.0)	1	1 (4.8)	1

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
General physical health deterioration	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Impaired healing	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Malaise	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Non-cardiac chest pain	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Blood and lymphatic system disorders	2 (50.0)	4	1 (14.3)	10	2 (20.0)	6	5 (23.8)	20
Lymphopenia	2 (50.0)	2	1 (14.3)	6	1 (10.0)	2	4 (19.0)	10
Anaemia	1 (25.0)	2	0	0	1 (10.0)	4	2 (9.5)	6
Neutropenia	0	0	1 (14.3)	4	0	0	1 (4.8)	4
Psychiatric disorders	0	0	1 (14.3)	1	4 (40.0)	5	5 (23.8)	6
Insomnia	0	0	0	0	2 (20.0)	2	2 (9.5)	2
Anxiety	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Confusional state	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Depression	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Mental status changes	0	0	0	0	1 (10.0)	1	1 (4.8)	1

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Renal and urinary disorders	2 (50.0)	2	0	0	2 (20.0)	4	4 (19.0)	6
Proteinuria	0	0	0	0	2 (20.0)	4	2 (9.5)	4
Haematuria	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Urinary incontinence	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Skin and subcutaneous tissue disorders	1 (25.0)	1	0	0	2 (20.0)	3	3 (14.3)	4
Decubitus ulcer	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Pruritus	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Skin disorder	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Uncoded	0	0	0	0	3 (30.0)	4	3 (14.3)	4
Uncoded	0	0	0	0	3 (30.0)	4	3 (14.3)	4
Cardiac disorders	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Angina pectoris	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Pericardial effusion	0	0	0	0	1 (10.0)	1	1 (4.8)	1

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

Table 14.3-1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Sinus tachycardia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Infections and infestations	0	0	0	0	2 (20.0)	2	2 (9.5)	2
Pneumonia aspiration	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Urinary tract infection	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Injury, poisoning and procedural complications	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Contusion	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Fall	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Vascular disorders	0	0	1 (14.3)	1	1 (10.0)	2	2 (9.5)	3
Hypertension	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Hypotension	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Cancer pain	0	0	0	0	1 (10.0)	1	1 (4.8)	1

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.3
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Reproductive system and breast disorders	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Perineal rash	0	0	0	0	1 (10.0)	2	1 (4.8)	2

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.6
Summary of Treatment-Emergent Adverse Events Related to NOX66 by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Patients with at least one TEAE related to NOX66	4 (100.0)	7	4 (57.1)	9	6 (60.0)	47	14 (66.7)	63
Gastrointestinal disorders	3 (75.0)	4	1 (14.3)	2	4 (40.0)	17	8 (38.1)	23
Diarrhoea	1 (25.0)	1	1 (14.3)	1	1 (10.0)	1	3 (14.3)	3
Anorectal discomfort	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Nausea	1 (25.0)	1	0	0	1 (10.0)	2	2 (9.5)	3
Proctitis	1 (25.0)	1	0	0	1 (10.0)	2	2 (9.5)	3
Abdominal distension	0	0	0	0	1 (10.0)	3	1 (4.8)	3
Anal pruritus	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Anal rash	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Proctalgia	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Rectal haemorrhage	0	0	0	0	1 (10.0)	3	1 (4.8)	3
Vomiting	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Investigations	0	0	2 (28.6)	5	2 (20.0)	7	4 (19.0)	12
Lymphocyte count decreased	0	0	2 (28.6)	3	2 (20.0)	5	4 (19.0)	8

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.6
Summary of Treatment-Emergent Adverse Events Related to NOX66 by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Blood alkaline phosphatase increased	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Neutrophil count decreased	0	0	1 (14.3)	1	0	0	1 (4.8)	1
White blood cell count decreased	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Blood and lymphatic system disorders	1 (25.0)	1	0	0	2 (20.0)	6	3 (14.3)	7
Anaemia	1 (25.0)	1	0	0	1 (10.0)	4	2 (9.5)	5
Lymphopenia	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Metabolism and nutrition disorders	0	0	1 (14.3)	2	2 (20.0)	4	3 (14.3)	6
Decreased appetite	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Hyperglycaemia	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Hyperkalaemia	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Hypoalbuminaemia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Hypophosphataemia	0	0	1 (14.3)	1	0	0	1 (4.8)	1
General disorders and administration site conditions	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

Table 14.3-1.6
Summary of Treatment-Emergent Adverse Events Related to NOX66 by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Fatigue	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Malaise	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Nervous system disorders	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Burning sensation	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Dizziness	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Skin and subcutaneous tissue disorders	1 (25.0)	1	0	0	1 (10.0)	2	2 (9.5)	3
Pruritus	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Skin disorder	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Cardiac disorders	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Sinus tachycardia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Renal and urinary disorders	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Proteinuria	0	0	0	0	1 (10.0)	2	1 (4.8)	2

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

/projects/noxop254919/stats/primary/prog/tables/t_teae.sas/04JUL2023/01:33

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Table 14.3-1.6
Summary of Treatment-Emergent Adverse Events Related to NOX66 by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Reproductive system and breast disorders	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Perineal rash	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Uncoded	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Uncoded	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Vascular disorders	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Hypotension	0	0	0	0	1 (10.0)	1	1 (4.8)	1

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Patients with at least one TEAE	4 (100.0)	23	7 (100.0)	62	9 (90.0)	133	20 (95.2)	218
Grade 1	3 (75.0)	14	1 (14.3)	34	1 (10.0)	89	5 (23.8)	137
Grade 2	0	6	1 (14.3)	20	3 (30.0)	32	4 (19.0)	58
Grade 3	0	2	4 (57.1)	7	4 (40.0)	11	8 (38.1)	20
Grade 4	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Grade 5	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Investigations	1 (25.0)	2	4 (57.1)	22	8 (80.0)	25	13 (61.9)	49
Grade 1	1 (25.0)	2	2 (28.6)	12	4 (40.0)	16	7 (33.3)	30
Grade 2	0	0	1 (14.3)	8	2 (20.0)	7	3 (14.3)	15
Grade 3	0	0	1 (14.3)	2	2 (20.0)	2	3 (14.3)	4
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Lymphocyte count decreased	0	0	2 (28.6)	7	5 (50.0)	11	7 (33.3)	18
Grade 1	0	0	0	3	1 (10.0)	4	1 (4.8)	7
Grade 2	0	0	1 (14.3)	2	2 (20.0)	5	3 (14.3)	7
Grade 3	0	0	1 (14.3)	2	2 (20.0)	2	3 (14.3)	4
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Blood alkaline phosphatase increased	0	0	0	0	2 (20.0)	4	2 (9.5)	4
Grade 1	0	0	0	0	2 (20.0)	4	2 (9.5)	4
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Blood creatinine increased	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
Grade 1	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Neutrophil count decreased	1 (25.0)	1	1 (14.3)	6	0	0	2 (9.5)	7
Grade 1	1 (25.0)	1	0	2	0	0	1 (4.8)	3
Grade 2	0	0	1 (14.3)	4	0	0	1 (4.8)	4
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
SARS-CoV-2 test positive	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
Grade 1	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
White blood cell count decreased	1 (25.0)	1	1 (14.3)	5	0	0	2 (9.5)	6
Grade 1	1 (25.0)	1	0	3	0	0	1 (4.8)	4
Grade 2	0	0	1 (14.3)	2	0	0	1 (4.8)	2
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Alanine aminotransferase increased	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Blood bicarbonate decreased	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Blood phosphorus decreased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Blood thyroid stimulating hormone increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Blood urea increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Brain natriuretic peptide increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Electrocardiogram ST segment elevation	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Gamma-glutamyltransferase increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Troponin increased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Weight decreased	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Metabolism and nutrition disorders	2 (50.0)	4	5 (71.4)	12	6 (60.0)	10	13 (61.9)	26
Grade 1	1 (25.0)	1	2 (28.6)	7	5 (50.0)	9	8 (38.1)	17
Grade 2	1 (25.0)	3	1 (14.3)	3	0	0	2 (9.5)	6
Grade 3	0	0	2 (28.6)	2	1 (10.0)	1	3 (14.3)	3
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Hypercalcaemia	0	0	3 (42.9)	5	1 (10.0)	1	4 (19.0)	6
Grade 1	0	0	3 (42.9)	5	1 (10.0)	1	4 (19.0)	6
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Dehydration	1 (25.0)	3	2 (28.6)	2	0	0	3 (14.3)	5
Grade 1	0	0	0	0	0	0	0	0
Grade 2	1 (25.0)	3	2 (28.6)	2	0	0	3 (14.3)	5
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Hyperglycaemia	0	0	0	0	2 (20.0)	5	2 (9.5)	5
Grade 1	0	0	0	0	2 (20.0)	5	2 (9.5)	5
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Hyperkalaemia	1 (25.0)	1	1 (14.3)	1	0	0	2 (9.5)	2
Grade 1	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Hypoalbuminaemia	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Decreased appetite	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Failure to thrive	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Hypokalaemia	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Hyponatraemia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Hypophagia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Hypophosphataemia	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Gastrointestinal disorders	3 (75.0)	5	1 (14.3)	2	7 (70.0)	29	11 (52.4)	36
Grade 1	2 (50.0)	4	1 (14.3)	2	2 (20.0)	20	5 (23.8)	26
Grade 2	1 (25.0)	1	0	0	3 (30.0)	7	4 (19.0)	8
Grade 3	0	0	0	0	2 (20.0)	2	2 (9.5)	2
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Nausea	2 (50.0)	2	0	0	4 (40.0)	5	6 (28.6)	7
Grade 1	1 (25.0)	1	0	0	3 (30.0)	4	4 (19.0)	5
Grade 2	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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If severity is missing it will be imputed as the highest grade.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Diarrhoea	1 (25.0)	1	1 (14.3)	1	2 (20.0)	2	4 (19.0)	4
Grade 1	1 (25.0)	1	1 (14.3)	1	1 (10.0)	1	3 (14.3)	3
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Anorectal discomfort	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Grade 1	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Proctitis	1 (25.0)	1	0	0	1 (10.0)	2	2 (9.5)	3
Grade 1	1 (25.0)	1	0	0	0	1	1 (4.8)	2
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Rectal haemorrhage	0	0	0	0	2 (20.0)	4	2 (9.5)	4
Grade 1	0	0	0	0	2 (20.0)	4	2 (9.5)	4
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Abdominal distension	0	0	0	0	1 (10.0)	3	1 (4.8)	3
Grade 1	0	0	0	0	0	2	0	2
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Anal pruritus	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Anal rash	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Constipation	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Dry mouth	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	0	1	0	1
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Dysphagia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Gastritis	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Hiatus hernia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Proctalgia	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Vomiting	0	0	0	0	1 (10.0)	3	1 (4.8)	3
Grade 1	0	0	0	0	0	2	0	2
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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AEs are classified according to MedDRA version 25.0.

/projects/noxop254919/stats/primary/prog/tables/t_teae_sev.sas/04JUL2023/01:33

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Musculoskeletal and connective tissue disorders	2 (50.0)	2	2 (28.6)	5	5 (50.0)	8	9 (42.9)	15
Grade 1	2 (50.0)	2	2 (28.6)	5	3 (30.0)	6	7 (33.3)	13
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Back pain	2 (50.0)	2	2 (28.6)	2	3 (30.0)	4	7 (33.3)	8
Grade 1	2 (50.0)	2	2 (28.6)	2	3 (30.0)	4	7 (33.3)	8
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Arthralgia	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Intervertebral disc protrusion	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Muscular weakness	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Myalgia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Osteoarthritis	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Pain in extremity	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Nervous system disorders	1 (25.0)	1	2 (28.6)	5	4 (40.0)	7	7 (33.3)	13
Grade 1	1 (25.0)	1	1 (14.3)	3	1 (10.0)	4	3 (14.3)	8
Grade 2	0	0	0	1	3 (30.0)	3	3 (14.3)	4
Grade 3	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Dizziness	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Grade 1	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Headache	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Grade 1	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Ageusia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Burning sensation	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	0	1	0	1
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Encephalopathy	0	0	1 (14.3)	2	0	0	1 (4.8)	2
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	1	0	0	0	1
Grade 3	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Hypoaesthesia	0	0	1 (14.3)	2	0	0	1 (4.8)	2
Grade 1	0	0	1 (14.3)	2	0	0	1 (4.8)	2
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Sensory loss	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	2 (28.6)	2	5 (50.0)	11	7 (33.3)	13
Grade 1	0	0	0	0	1 (10.0)	6	1 (4.8)	6
Grade 2	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Grade 3	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
Grade 4	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 5	0	0	1 (14.3)	1	0	0	1 (4.8)	1

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Dyspnoea	0	0	0	0	3 (30.0)	4	3 (14.3)	4
Grade 1	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Acute respiratory failure	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	1 (14.3)	1	0	0	1 (4.8)	1

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Asphyxia	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Cough	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Oropharyngeal pain	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	0	1	0	1
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Pleural effusion	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

/projects/noxop254919/stats/primary/prog/tables/t_teae_sev.sas/04JUL2023/01:33

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Respiratory distress	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 5	0	0	0	0	0	0	0	0
Tachypnoea	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
General disorders and administration site conditions	1 (25.0)	2	2 (28.6)	2	3 (30.0)	8	6 (28.6)	12
Grade 1	0	0	2 (28.6)	2	1 (10.0)	5	3 (14.3)	7
Grade 2	0	1	0	0	1 (10.0)	2	1 (4.8)	3
Grade 3	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Fatigue	1 (25.0)	1	2 (28.6)	2	2 (20.0)	3	5 (23.8)	6
Grade 1	0	0	2 (28.6)	2	1 (10.0)	2	3 (14.3)	4
Grade 2	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Asthenia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
General physical health deterioration	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Impaired healing	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Malaise	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	0	1	0	1
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Non-cardiac chest pain	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Blood and lymphatic system disorders	2 (50.0)	4	1 (14.3)	10	2 (20.0)	6	5 (23.8)	20
Grade 1	1 (25.0)	1	0	3	0	3	1 (4.8)	7
Grade 2	0	1	0	6	2 (20.0)	3	2 (9.5)	10
Grade 3	0	1	1 (14.3)	1	0	0	1 (4.8)	2
Grade 4	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Lymphopenia	2 (50.0)	2	1 (14.3)	6	1 (10.0)	2	4 (19.0)	10
Grade 1	1 (25.0)	1	0	3	0	1	1 (4.8)	5
Grade 2	1 (25.0)	1	1 (14.3)	3	1 (10.0)	1	3 (14.3)	5
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Anaemia	1 (25.0)	2	0	0	1 (10.0)	4	2 (9.5)	6
Grade 1	0	0	0	0	0	2	0	2
Grade 2	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 3	0	1	0	0	0	0	0	1
Grade 4	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Neutropenia	0	0	1 (14.3)	4	0	0	1 (4.8)	4
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	3	0	0	0	3
Grade 3	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Psychiatric disorders	0	0	1 (14.3)	1	4 (40.0)	5	5 (23.8)	6
Grade 1	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Grade 2	0	0	1 (14.3)	1	1 (10.0)	1	2 (9.5)	2
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Insomnia	0	0	0	0	2 (20.0)	2	2 (9.5)	2
Grade 1	0	0	0	0	2 (20.0)	2	2 (9.5)	2
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Anxiety	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Confusional state	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Depression	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

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For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Mental status changes	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Renal and urinary disorders	2 (50.0)	2	0	0	2 (20.0)	4	4 (19.0)	6
Grade 1	2 (50.0)	2	0	0	2 (20.0)	4	4 (19.0)	6
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Proteinuria	0	0	0	0	2 (20.0)	4	2 (9.5)	4
Grade 1	0	0	0	0	2 (20.0)	4	2 (9.5)	4
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Haematuria	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 1	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Urinary incontinence	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 1	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	1 (25.0)	1	0	0	2 (20.0)	3	3 (14.3)	4
Grade 1	1 (25.0)	1	0	0	2 (20.0)	3	3 (14.3)	4
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

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E = Number of events; Percentage (%) = $n/N \times 100$.

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For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Decubitus ulcer	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Pruritus	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Skin disorder	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 1	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Uncoded	0	0	0	0	3 (30.0)	4	3 (14.3)	4
Grade 1	0	0	0	0	3 (30.0)	4	3 (14.3)	4
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Uncoded	0	0	0	0	3 (30.0)	4	3 (14.3)	4
Grade 1	0	0	0	0	3 (30.0)	4	3 (14.3)	4
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Cardiac disorders	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	1	0	1
Grade 3	0	0	0	0	2 (20.0)	2	2 (9.5)	2
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Angina pectoris	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Pericardial effusion	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Sinus tachycardia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Infections and infestations	0	0	0	0	2 (20.0)	2	2 (9.5)	2
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Pneumonia aspiration	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Urinary tract infection	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N * 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Injury, poisoning and procedural complications	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Grade 1	0	0	0	0	2 (20.0)	3	2 (9.5)	3
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Contusion	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Fall	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Vascular disorders	0	0	1 (14.3)	1	1 (10.0)	2	2 (9.5)	3
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	1 (14.3)	1	1 (10.0)	2	2 (9.5)	3
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Hypertension	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Hypotension	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Cancer pain	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 1	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-1.13
Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term and Severity
(Safety Set)

System Order Class Preferred Term Grade	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Reproductive system and breast disorders	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	0	1	0	1
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0
Perineal rash	0	0	0	0	1 (10.0)	2	1 (4.8)	2
Grade 1	0	0	0	0	0	1	0	1
Grade 2	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Grade 5	0	0	0	0	0	0	0	0

TEAE = treatment-emergent adverse event; N = number of patients in the analysis set; n = number of patients in the specified category;
E = Number of events; Percentage (%) = $n/N \times 100$.

If severity is missing it will be imputed as the highest grade.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred with the worst severity even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

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Table 14.3-2.2
Summary of Treatment Emergent Serious Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Patients with at least one TESAE	1 (25.0)	2	3 (42.9)	4	4 (40.0)	7	8 (38.1)	13
Respiratory, thoracic and mediastinal disorders	0	0	2 (28.6)	2	1 (10.0)	1	3 (14.3)	3
Acute respiratory failure	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Pleural effusion	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Respiratory distress	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Cardiac disorders	0	0	0	0	2 (20.0)	2	2 (9.5)	2
Angina pectoris	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Sinus tachycardia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
General disorders and administration site conditions	1 (25.0)	1	0	0	1 (10.0)	1	2 (9.5)	2
General physical health deterioration	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Non-cardiac chest pain	1 (25.0)	1	0	0	0	0	1 (4.8)	1

TEAE = Treatment emergent adverse event; TESAE = Treatment emergent serious adverse event; N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = $n/N \times 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

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Table 14.3-2.2
Summary of Treatment Emergent Serious Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Blood and lymphatic system disorders	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Anaemia	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Gastrointestinal disorders	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Diarrhoea	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Metabolism and nutrition disorders	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Failure to thrive	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Musculoskeletal and connective tissue disorders	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Pain in extremity	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Nervous system disorders	0	0	1 (14.3)	1	0	0	1 (4.8)	1
Encephalopathy	0	0	1 (14.3)	1	0	0	1 (4.8)	1

TEAE = Treatment emergent adverse event; TESAE = Treatment emergent serious adverse event; N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = n/N * 100.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-2.2
Summary of Treatment Emergent Serious Adverse Events by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Psychiatric disorders	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Confusional state	0	0	0	0	1 (10.0)	1	1 (4.8)	1

TEAE = Treatment emergent adverse event; TESAE = Treatment emergent serious adverse event; N = number of patients in the analysis set;
n = number of patients in the specified category; E = Number of events; Percentage (%) = $n/N * 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

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Table 14.3-2.3
Summary of Treatment Emergent Serious Adverse Events Related to NOX66 by System Organ Class and Preferred Term
(Safety Set)

System Order Class Preferred Term	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	n (%)	E	n (%)	E	n (%)	E	n (%)	E
Patients with at least one TESAE related to NOX66	1 (25.0)	1	0	0	2 (20.0)	2	3 (14.3)	3
Blood and lymphatic system disorders	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Anaemia	1 (25.0)	1	0	0	0	0	1 (4.8)	1
Cardiac disorders	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Sinus tachycardia	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Gastrointestinal disorders	0	0	0	0	1 (10.0)	1	1 (4.8)	1
Diarrhoea	0	0	0	0	1 (10.0)	1	1 (4.8)	1

TEAE = Treatment emergent adverse event; TESAE = Treatment emergent serious adverse event; N = number of patients in the analysis set; n = number of patients in the specified category; E = Number of events; Percentage (%) = $n/N \times 100$.

For the summarization of number of patients (n), a patient is counted only once for each system organ class and preferred even if he/she reported one or more events. For the summarization of number of events (E), the number of AEs counts all AEs of each patient under each SOC and each PT.

Treatment-emergent AEs (TEAEs) are defined as those AEs that either start or worsen in severity on or after the date of first administration of study drug and on or before 30 days after the last dose of study drug.

AEs are classified according to MedDRA version 25.0.

Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Platelets (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value			Value		Value		Value	
Baseline								
Nx	4		7		10		21	
Mean	204.0		301.6		311.7		287.8	
SD	70.00		158.95		127.22		131.74	
Median	229.0		255.0		296.0		250.0	
Q1, Q3	157.0, 251.0		206.0, 376.0		207.0, 409.0		207.0, 376.0	
Min, Max	103, 255		154, 625		139, 499		103, 625	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	200.3	-1.3	265.0	-24.2	308.4	-3.3	277.6	-9.6
SD	90.78	25.01	177.97	26.92	131.62	29.85	141.24	28.64
Median	221.0	-2.0	194.5	-10.5	299.0	-7.5	221.0	-8.0
Q1, Q3	101.0, 279.0	-26.0, 24.0	162.0, 270.0	-44.0, -7.0	213.0, 403.0	-19.0, 12.0	162.0, 394.0	-26.0, -2.0
Min, Max	101, 279	-26, 24	151, 618	-70, -3	136, 511	-41, 61	101, 618	-70, 61

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Platelets (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	251.3	49.7	184.0	-42.0	255.6	-49.0	234.2	-25.9
SD	131.04	54.22	31.44	32.89	106.95	77.26	96.12	71.71
Median	281.0	34.0	194.5	-32.5	207.0	-21.0	205.5	-17.5
Q1, Q3	108.0, 365.0	5.0, 110.0	165.5, 202.5	-66.5, -17.5	186.0, 392.0	-89.0, -8.0	186.0, 281.0	-46.0, 5.0
Min, Max	108, 365	5, 110	138, 209	-87, -16	128, 410	-202, 34	108, 410	-202, 110
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	205.5	26.5	181.3	-44.8	275.1	-43.3	238.4	-33.7
SD	119.50	12.02	29.06	34.64	125.37	86.60	108.43	70.55
Median	205.5	26.5	181.5	-40.5	225.5	-19.5	211.0	-19.5
Q1, Q3	121.0, 290.0	18.0, 35.0	159.0, 203.5	-66.0, -23.5	201.0, 355.5	-94.0, 16.0	171.0, 290.0	-52.0, 18.0
Min, Max	121, 290	18, 35	147, 215	-91, -7	122, 515	-202, 51	121, 515	-202, 51

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Platelets (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	339.0	84.0	228.3	2.3	289.0	-16.5	271.5	-0.5
SD	NC	NC	56.54	31.46	119.32	79.33	97.29	65.68
Median	339.0	84.0	242.0	-4.0	240.5	17.0	246.0	13.0
Q1, Q3	339.0, 339.0	84.0, 84.0	188.0, 268.5	-16.5, 21.0	228.0, 422.0	-48.0, 22.0	226.0, 339.0	-29.0, 46.0
Min, Max	339, 339	84, 84	150, 279	-29, 46	152, 451	-163, 56	150, 451	-163, 84
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	365.0	110.0	225.5	-0.5	265.8	-20.8	259.6	0.4
SD	NC	NC	66.88	16.52	100.43	64.29	88.01	59.27
Median	365.0	110.0	223.5	-7.0	228.0	19.0	235.5	6.5
Q1, Q3	365.0, 365.0	110.0, 110.0	176.0, 275.0	-10.0, 9.0	216.0, 310.0	-82.0, 21.0	204.0, 310.0	-12.0, 24.0
Min, Max	365, 365	110, 110	148, 307	-12, 24	158, 417	-99, 37	148, 417	-99, 110

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Platelets (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	214.3	-11.8	264.2	-22.4	242.0	-17.7
SD	NC	NC	51.05	10.63	139.12	75.20	106.53	53.86
Median	NC	NC	228.0	-11.5	206.0	7.0	213.0	-1.0
Q1, Q3	NC, NC	NC, NC	178.0, 250.5	-18.5, -5.0	195.0, 253.0	-1.0, 16.0	195.0, 253.0	-12.0, 7.0
Min, Max	NC, NC	NC, NC	143, 258	-25, 1	161, 506	-156, 22	143, 506	-156, 22
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	217.7	-32.3	199.0	-43.3	208.3	-37.8
SD	NC	NC	27.50	28.92	89.40	56.89	60.04	40.81
Median	NC	NC	218.0	-22.0	167.0	-12.0	204.0	-17.0
Q1, Q3	NC, NC	NC, NC	190.0, 245.0	-65.0, -10.0	130.0, 300.0	-109.0, -9.0	167.0, 245.0	-65.0, -10.0
Min, Max	NC, NC	NC, NC	190, 245	-65, -10	130, 300	-109, -9	130, 300	-109, -9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Platelets (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	226.7	-23.3	177.0	18.0	206.8	-6.8
SD	NC	NC	35.53	16.29	12.73	15.56	37.57	26.57
Median	NC	NC	213.0	-16.0	177.0	18.0	200.0	-12.0
Q1, Q3	NC, NC	NC, NC	200.0, 267.0	-42.0, -12.0	168.0, 186.0	7.0, 29.0	186.0, 213.0	-16.0, 7.0
Min, Max	NC, NC	NC, NC	200, 267	-42, -12	168, 186	7, 29	168, 267	-42, 29
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	222.0	-33.0	171.0	12.0	188.0	-3.0
SD	NC	NC	NC	NC	36.77	8.49	39.28	26.66
Median	NC	NC	222.0	-33.0	171.0	12.0	197.0	6.0
Q1, Q3	NC, NC	NC, NC	222.0, 222.0	-33.0, -33.0	145.0, 197.0	6.0, 18.0	145.0, 222.0	-33.0, 18.0
Min, Max	NC, NC	NC, NC	222, 222	-33, -33	145, 197	6, 18	145, 222	-33, 18

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Platelets (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	209.0	-46.0	133.0	-6.0	171.0	-26.0
SD	NC	NC	NC	NC	NC	NC	53.74	28.28
Median	NC	NC	209.0	-46.0	133.0	-6.0	171.0	-26.0
Q1, Q3	NC, NC	NC, NC	209.0, 209.0	-46.0, -46.0	133.0, 133.0	-6.0, -6.0	133.0, 209.0	-46.0, -6.0
Min, Max	NC, NC	NC, NC	209, 209	-46, -46	133, 133	-6, -6	133, 209	-46, -6
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	218.0	-37.0	155.0	16.0	186.5	-10.5
SD	NC	NC	NC	NC	NC	NC	44.55	37.48
Median	NC	NC	218.0	-37.0	155.0	16.0	186.5	-10.5
Q1, Q3	NC, NC	NC, NC	218.0, 218.0	-37.0, -37.0	155.0, 155.0	16.0, 16.0	155.0, 218.0	-37.0, 16.0
Min, Max	NC, NC	NC, NC	218, 218	-37, -37	155, 155	16, 16	155, 218	-37, 16

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Platelets (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	257.0	2.0	131.0	-8.0	194.0	-3.0
SD	NC	NC	NC	NC	NC	NC	89.10	7.07
Median	NC	NC	257.0	2.0	131.0	-8.0	194.0	-3.0
Q1, Q3	NC, NC	NC, NC	257.0, 257.0	2.0, 2.0	131.0, 131.0	-8.0, -8.0	131.0, 257.0	-8.0, 2.0
Min, Max	NC, NC	NC, NC	257, 257	2, 2	131, 131	-8, -8	131, 257	-8, 2
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	220.0	-35.0	NC	NC	220.0	-35.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	220.0	-35.0	NC	NC	220.0	-35.0
Q1, Q3	NC, NC	NC, NC	220.0, 220.0	-35.0, -35.0	NC, NC	NC, NC	220.0, 220.0	-35.0, -35.0
Min, Max	NC, NC	NC, NC	220, 220	-35, -35	NC, NC	NC, NC	220, 220	-35, -35

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Platelets (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	232.0	-23.0	NC	NC	232.0	-23.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	232.0	-23.0	NC	NC	232.0	-23.0
Q1, Q3	NC, NC	NC, NC	232.0, 232.0	-23.0, -23.0	NC, NC	NC, NC	232.0, 232.0	-23.0, -23.0
Min, Max	NC, NC	NC, NC	232, 232	-23, -23	NC, NC	NC, NC	232, 232	-23, -23
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	218.0	-37.0	NC	NC	218.0	-37.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	218.0	-37.0	NC	NC	218.0	-37.0
Q1, Q3	NC, NC	NC, NC	218.0, 218.0	-37.0, -37.0	NC, NC	NC, NC	218.0, 218.0	-37.0, -37.0
Min, Max	NC, NC	NC, NC	218, 218	-37, -37	NC, NC	NC, NC	218, 218	-37, -37

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Platelets (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	234.3	32.7	206.0	-20.0	301.9	5.0	262.8	3.9
SD	151.68	72.98	50.31	25.59	156.46	29.82	134.30	41.07
Median	270.0	23.0	192.5	-25.0	223.5	-1.0	222.0	-3.0
Q1, Q3	68.0, 365.0	-35.0, 110.0	168.0, 244.0	-41.0, 1.0	194.5, 455.0	-6.5, 4.5	171.0, 365.0	-28.0, 11.0
Min, Max	68, 365	-35, 110	165, 274	-41, 11	131, 538	-28, 74	68, 538	-41, 110

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Erythrocytes ($10^{12}/L$)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	3.853		4.021		4.114		4.033	
SD	0.6367		0.5439		0.7052		0.6190	
Median	4.100		4.000		4.080		4.050	
Q1, Q3	3.480, 4.225		3.590, 4.150		3.490, 4.470		3.590, 4.260	
Min, Max	2.91, 4.30		3.54, 5.11		3.31, 5.70		2.91, 5.70	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	3.747	-0.040	3.978	-0.123	4.089	-0.025	4.000	-0.058
SD	0.9949	0.2700	0.5790	0.0829	0.7006	0.2460	0.6810	0.2058
Median	4.260	-0.040	3.955	-0.125	4.085	-0.025	4.000	-0.070
Q1, Q3	2.600, 4.380	-0.310, 0.230	3.490, 4.080	-0.210, -0.070	3.560, 4.500	-0.130, 0.170	3.490, 4.380	-0.210, 0.070
Min, Max	2.60, 4.38	-0.31, 0.23	3.38, 5.01	-0.21, 0.00	3.03, 5.30	-0.40, 0.30	2.60, 5.30	-0.40, 0.30

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Erythrocytes ($10^{12}/L$)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	3.643	-0.143	4.010	-0.215	3.720	-0.169	3.786	-0.176
SD	0.9905	0.2363	0.6929	0.2615	0.4813	0.1727	0.6254	0.1972
Median	4.190	-0.060	4.055	-0.220	3.890	-0.200	4.005	-0.170
Q1, Q3	2.500, 4.240	-0.410, 0.040	3.565, 4.455	-0.410, -0.020	3.300, 4.150	-0.320, -0.010	3.300, 4.190	-0.320, -0.010
Min, Max	2.50, 4.24	-0.41, 0.04	3.12, 4.81	-0.52, 0.10	3.09, 4.31	-0.40, 0.10	2.50, 4.81	-0.52, 0.10
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	4.365	0.140	4.000	-0.225	3.836	-0.338	3.959	-0.237
SD	0.0636	0.0424	0.6999	0.2403	0.7923	0.2774	0.6975	0.2881
Median	4.365	0.140	3.990	-0.260	3.540	-0.280	3.990	-0.255
Q1, Q3	4.320, 4.410	0.110, 0.170	3.520, 4.480	-0.375, -0.075	3.325, 4.305	-0.570, -0.125	3.340, 4.400	-0.480, 0.030
Min, Max	4.32, 4.41	0.11, 0.17	3.16, 4.86	-0.48, 0.10	2.95, 5.40	-0.78, 0.03	2.95, 5.40	-0.78, 0.17

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Erythrocytes ($10^{12}/L$)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	4.420	0.120	4.068	-0.158	3.923	-0.120	4.021	-0.112
SD	NC	NC	0.5923	0.1940	0.5360	0.1717	0.5210	0.1797
Median	4.420	0.120	4.085	-0.155	4.015	-0.090	4.170	-0.080
Q1, Q3	4.420, 4.420	0.120, 0.120	3.665, 4.470	-0.325, 0.010	3.390, 4.300	-0.170, 0.000	3.390, 4.420	-0.310, 0.020
Min, Max	4.42, 4.42	0.12, 0.12	3.33, 4.77	-0.34, 0.02	3.23, 4.59	-0.43, 0.06	3.23, 4.77	-0.43, 0.12
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	4.360	0.060	4.048	-0.178	4.418	0.472	4.264	0.171
SD	NC	NC	0.6354	0.2674	0.8773	1.1878	0.7153	0.8698
Median	4.360	0.060	4.125	-0.185	4.110	-0.080	4.130	-0.040
Q1, Q3	4.360, 4.360	0.060, 0.060	3.650, 4.445	-0.405, 0.050	4.100, 4.390	-0.100, 0.100	4.100, 4.390	-0.150, 0.100
Min, Max	4.36, 4.36	0.06, 0.06	3.20, 4.74	-0.44, 0.10	3.59, 5.90	-0.15, 2.59	3.20, 5.90	-0.44, 2.59

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Erythrocytes (10¹²/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	4.273	0.048	3.796	-0.150	4.008	-0.062
SD	NC	NC	0.6080	0.1873	0.6452	0.2216	0.6402	0.2203
Median	NC	NC	4.270	0.005	4.000	-0.150	4.100	-0.090
Q1, Q3	NC, NC	NC, NC	3.825, 4.720	-0.100, 0.195	3.270, 4.110	-0.200, -0.040	3.550, 4.440	-0.150, 0.100
Min, Max	NC, NC	NC, NC	3.55, 5.00	-0.11, 0.29	3.01, 4.59	-0.48, 0.12	3.01, 5.00	-0.48, 0.29
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	4.290	-0.010	3.547	-0.140	3.918	-0.075
SD	NC	NC	0.8107	0.1808	0.8103	0.5220	0.8315	0.3566
Median	NC	NC	4.330	-0.030	3.520	0.110	3.925	0.040
Q1, Q3	NC, NC	NC, NC	3.460, 5.080	-0.180, 0.180	2.750, 4.370	-0.740, 0.210	3.460, 4.370	-0.180, 0.180
Min, Max	NC, NC	NC, NC	3.46, 5.08	-0.18, 0.18	2.75, 4.37	-0.74, 0.21	2.75, 5.08	-0.74, 0.21

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Erythrocytes (10¹²/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	4.290	-0.010	3.790	0.005	4.090	-0.004
SD	NC	NC	0.6609	0.1808	0.4808	0.1909	0.5926	0.1598
Median	NC	NC	4.330	-0.030	3.790	0.005	4.130	-0.030
Q1, Q3	NC, NC	NC, NC	3.610, 4.930	-0.180, 0.180	3.450, 4.130	-0.130, 0.140	3.610, 4.330	-0.130, 0.140
Min, Max	NC, NC	NC, NC	3.61, 4.93	-0.18, 0.18	3.45, 4.13	-0.13, 0.14	3.45, 4.93	-0.18, 0.18
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	4.190	0.040	4.100	0.315	4.130	0.223
SD	NC	NC	NC	NC	0.3818	0.2899	0.2750	0.2593
Median	NC	NC	4.190	0.040	4.100	0.315	4.190	0.110
Q1, Q3	NC, NC	NC, NC	4.190, 4.190	0.040, 0.040	3.830, 4.370	0.110, 0.520	3.830, 4.370	0.040, 0.520
Min, Max	NC, NC	NC, NC	4.19, 4.19	0.04, 0.04	3.83, 4.37	0.11, 0.52	3.83, 4.37	0.04, 0.52

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Erythrocytes (10¹²/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	4.370	0.220	3.840	0.530	4.105	0.375
SD	NC	NC	NC	NC	NC	NC	0.3748	0.2192
Median	NC	NC	4.370	0.220	3.840	0.530	4.105	0.375
Q1, Q3	NC, NC	NC, NC	4.370, 4.370	0.220, 0.220	3.840, 3.840	0.530, 0.530	3.840, 4.370	0.220, 0.530
Min, Max	NC, NC	NC, NC	4.37, 4.37	0.22, 0.22	3.84, 3.84	0.53, 0.53	3.84, 4.37	0.22, 0.53
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	4.430	0.280	3.530	0.220	3.980	0.250
SD	NC	NC	NC	NC	NC	NC	0.6364	0.0424
Median	NC	NC	4.430	0.280	3.530	0.220	3.980	0.250
Q1, Q3	NC, NC	NC, NC	4.430, 4.430	0.280, 0.280	3.530, 3.530	0.220, 0.220	3.530, 4.430	0.220, 0.280
Min, Max	NC, NC	NC, NC	4.43, 4.43	0.28, 0.28	3.53, 3.53	0.22, 0.22	3.53, 4.43	0.22, 0.28

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Erythrocytes (10¹²/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	4.720	0.570	3.710	0.400	4.215	0.485
SD	NC	NC	NC	NC	NC	NC	0.7142	0.1202
Median	NC	NC	4.720	0.570	3.710	0.400	4.215	0.485
Q1, Q3	NC, NC	NC, NC	4.720, 4.720	0.570, 0.570	3.710, 3.710	0.400, 0.400	3.710, 4.720	0.400, 0.570
Min, Max	NC, NC	NC, NC	4.72, 4.72	0.57, 0.57	3.71, 3.71	0.40, 0.40	3.71, 4.72	0.40, 0.57
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.380	0.230	NC	NC	4.380	0.230
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.380	0.230	NC	NC	4.380	0.230
Q1, Q3	NC, NC	NC, NC	4.380, 4.380	0.230, 0.230	NC, NC	NC, NC	4.380, 4.380	0.230, 0.230
Min, Max	NC, NC	NC, NC	4.38, 4.38	0.23, 0.23	NC, NC	NC, NC	4.38, 4.38	0.23, 0.23

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Erythrocytes (10¹²/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.220	0.070	NC	NC	4.220	0.070
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.220	0.070	NC	NC	4.220	0.070
Q1, Q3	NC, NC	NC, NC	4.220, 4.220	0.070, 0.070	NC, NC	NC, NC	4.220, 4.220	0.070, 0.070
Min, Max	NC, NC	NC, NC	4.22, 4.22	0.07, 0.07	NC, NC	NC, NC	4.22, 4.22	0.07, 0.07
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.360	0.210	NC	NC	4.360	0.210
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.360	0.210	NC	NC	4.360	0.210
Q1, Q3	NC, NC	NC, NC	4.360, 4.360	0.210, 0.210	NC, NC	NC, NC	4.360, 4.360	0.210, 0.210
Min, Max	NC, NC	NC, NC	4.36, 4.36	0.21, 0.21	NC, NC	NC, NC	4.36, 4.36	0.21, 0.21

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Erythrocytes (10¹²/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	4.153	0.367	4.218	-0.008	3.968	-0.114	4.071	0.011
SD	0.6549	0.2658	0.5294	0.2095	0.4917	0.3618	0.5059	0.3479
Median	4.360	0.510	4.230	0.015	3.895	-0.170	3.960	0.060
Q1, Q3	3.420, 4.680	0.060, 0.530	3.835, 4.600	-0.170, 0.155	3.685, 4.110	-0.335, 0.200	3.660, 4.360	-0.270, 0.230
Min, Max	3.42, 4.68	0.06, 0.53	3.57, 4.84	-0.27, 0.21	3.36, 5.00	-0.70, 0.40	3.36, 5.00	-0.70, 0.53

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hemoglobin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Baseline								
Nx	4		7		10		21	
Mean	108.5		115.7		118.4		115.6	
SD	16.78		16.32		17.72		16.65	
Median	114.0		112.0		117.0		113.0	
Q1, Q3	98.5, 118.5		102.0, 138.0		104.0, 137.0		104.0, 122.0	
Min, Max	84, 122		101, 139		92, 142		84, 142	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	104.0	-2.3	114.0	-4.0	118.0	-0.4	114.5	-1.8
SD	28.21	9.29	18.18	3.69	19.27	7.00	19.78	6.37
Median	108.0	-5.0	111.5	-5.0	119.0	-0.5	116.0	-2.0
Q1, Q3	74.0, 130.0	-10.0, 8.0	99.0, 133.0	-5.0, -2.0	111.0, 127.0	-6.0, 5.0	99.0, 130.0	-6.0, 5.0
Min, Max	74, 130	-10, 8	92, 137	-9, 2	81, 151	-11, 9	74, 151	-11, 9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hemoglobin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	100.3	-6.0	119.8	-6.0	109.1	-5.6	110.3	-5.8
SD	27.93	8.54	17.73	9.02	17.69	4.79	19.70	6.38
Median	106.0	-7.0	125.0	-6.0	100.0	-5.0	110.0	-6.0
Q1, Q3	70.0, 125.0	-14.0, 3.0	107.0, 132.5	-12.0, 0.0	98.0, 131.0	-11.0, -2.0	98.0, 131.0	-11.0, -2.0
Min, Max	70, 125	-14, 3	95, 134	-17, 5	88, 134	-11, 2	70, 134	-17, 5
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	119.0	1.5	117.8	-8.0	108.4	-10.4	112.6	-8.0
SD	15.56	9.19	16.50	6.58	19.07	6.99	17.40	7.76
Median	119.0	1.5	121.5	-8.0	100.5	-10.0	111.0	-9.0
Q1, Q3	108.0, 130.0	-5.0, 8.0	105.0, 130.5	-12.5, -3.5	93.0, 130.0	-14.5, -6.5	97.0, 130.0	-14.0, -4.0
Min, Max	108, 130	-5, 8	96, 132	-16, 0	88, 132	-22, 1	88, 132	-22, 8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hemoglobin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	108.0	-5.0	122.0	-3.8	114.7	-5.5	116.7	-4.8
SD	NC	NC	16.25	5.68	16.67	5.21	15.47	4.90
Median	108.0	-5.0	124.0	-3.5	110.0	-5.0	112.0	-5.0
Q1, Q3	108.0, 108.0	-5.0, -5.0	109.0, 135.0	-8.5, 1.0	102.0, 134.0	-8.0, -2.0	102.0, 134.0	-8.0, 0.0
Min, Max	108, 108	-5, -5	102, 138	-10, 2	96, 136	-14, 1	96, 138	-14, 2
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	103.0	-10.0	121.5	-4.3	114.8	-1.0	116.3	-3.2
SD	NC	NC	16.52	7.50	15.64	6.04	15.25	6.58
Median	103.0	-10.0	124.0	-4.5	115.0	-2.0	116.5	-3.0
Q1, Q3	103.0, 103.0	-10.0, -10.0	109.0, 134.0	-10.5, 2.0	102.0, 120.0	-4.0, -1.0	102.0, 130.0	-9.0, 0.0
Min, Max	103, 103	-10, -10	100, 138	-12, 4	99, 138	-7, 9	99, 138	-12, 9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hemoglobin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	126.8	1.0	110.4	-5.4	117.7	-2.6
SD	NC	NC	17.08	4.97	20.83	6.11	20.01	6.27
Median	NC	NC	125.5	-0.5	99.0	-5.0	115.0	-3.0
Q1, Q3	NC, NC	NC, NC	112.5, 141.0	-2.5, 4.5	97.0, 115.0	-7.0, -4.0	99.0, 136.0	-5.0, 1.0
Min, Max	NC, NC	NC, NC	110, 146	-3, 8	96, 145	-14, 3	96, 146	-14, 8
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	129.7	0.0	103.3	-7.7	116.5	-3.8
SD	NC	NC	19.66	4.58	16.04	13.43	21.58	9.91
Median	NC	NC	140.0	1.0	102.0	-2.0	113.5	-0.5
Q1, Q3	NC, NC	NC, NC	107.0, 142.0	-5.0, 4.0	88.0, 120.0	-23.0, 2.0	102.0, 140.0	-5.0, 2.0
Min, Max	NC, NC	NC, NC	107, 142	-5, 4	88, 120	-23, 2	88, 142	-23, 4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hemoglobin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	130.0	0.3	106.0	-5.0	120.4	-1.8
SD	NC	NC	15.87	3.51	9.90	5.66	17.98	4.76
Median	NC	NC	136.0	0.0	106.0	-5.0	113.0	-1.0
Q1, Q3	NC, NC	NC, NC	112.0, 142.0	-3.0, 4.0	99.0, 113.0	-9.0, -1.0	112.0, 136.0	-3.0, 0.0
Min, Max	NC, NC	NC, NC	112, 142	-3, 4	99, 113	-9, -1	99, 142	-9, 4
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	139.0	1.0	118.0	7.0	125.0	5.0
SD	NC	NC	NC	NC	8.49	7.07	13.53	6.08
Median	NC	NC	139.0	1.0	118.0	7.0	124.0	2.0
Q1, Q3	NC, NC	NC, NC	139.0, 139.0	1.0, 1.0	112.0, 124.0	2.0, 12.0	112.0, 139.0	1.0, 12.0
Min, Max	NC, NC	NC, NC	139, 139	1, 1	112, 124	2, 12	112, 139	1, 12

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hemoglobin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	145.0	7.0	112.0	12.0	128.5	9.5
SD	NC	NC	NC	NC	NC	NC	23.33	3.54
Median	NC	NC	145.0	7.0	112.0	12.0	128.5	9.5
Q1, Q3	NC, NC	NC, NC	145.0, 145.0	7.0, 7.0	112.0, 112.0	12.0, 12.0	112.0, 145.0	7.0, 12.0
Min, Max	NC, NC	NC, NC	145, 145	7, 7	112, 112	12, 12	112, 145	7, 12
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	147.0	9.0	104.0	4.0	125.5	6.5
SD	NC	NC	NC	NC	NC	NC	30.41	3.54
Median	NC	NC	147.0	9.0	104.0	4.0	125.5	6.5
Q1, Q3	NC, NC	NC, NC	147.0, 147.0	9.0, 9.0	104.0, 104.0	4.0, 4.0	104.0, 147.0	4.0, 9.0
Min, Max	NC, NC	NC, NC	147, 147	9, 9	104, 104	4, 4	104, 147	4, 9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hemoglobin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	156.0	18.0	109.0	9.0	132.5	13.5
SD	NC	NC	NC	NC	NC	NC	33.23	6.36
Median	NC	NC	156.0	18.0	109.0	9.0	132.5	13.5
Q1, Q3	NC, NC	NC, NC	156.0, 156.0	18.0, 18.0	109.0, 109.0	9.0, 9.0	109.0, 156.0	9.0, 18.0
Min, Max	NC, NC	NC, NC	156, 156	18, 18	109, 109	9, 9	109, 156	9, 18
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	146.0	8.0	NC	NC	146.0	8.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	146.0	8.0	NC	NC	146.0	8.0
Q1, Q3	NC, NC	NC, NC	146.0, 146.0	8.0, 8.0	NC, NC	NC, NC	146.0, 146.0	8.0, 8.0
Min, Max	NC, NC	NC, NC	146, 146	8, 8	NC, NC	NC, NC	146, 146	8, 8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hemoglobin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	139.0	1.0	NC	NC	139.0	1.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	139.0	1.0	NC	NC	139.0	1.0
Q1, Q3	NC, NC	NC, NC	139.0, 139.0	1.0, 1.0	NC, NC	NC, NC	139.0, 139.0	1.0, 1.0
Min, Max	NC, NC	NC, NC	139, 139	1, 1	NC, NC	NC, NC	139, 139	1, 1
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	145.0	7.0	NC	NC	145.0	7.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	145.0	7.0	NC	NC	145.0	7.0
Q1, Q3	NC, NC	NC, NC	145.0, 145.0	7.0, 7.0	NC, NC	NC, NC	145.0, 145.0	7.0, 7.0
Min, Max	NC, NC	NC, NC	145, 145	7, 7	NC, NC	NC, NC	145, 145	7, 7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hemoglobin (g/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	114.0	7.7	127.5	1.8	111.1	-3.9	116.1	-0.1
SD	23.52	15.50	14.71	5.12	13.04	7.34	16.21	9.43
Median	103.0	14.0	126.0	2.5	109.5	-5.5	113.0	-2.0
Q1, Q3	98.0, 141.0	-10.0, 19.0	115.5, 139.5	-2.0, 5.5	102.0, 117.5	-7.5, 0.5	103.0, 134.0	-6.0, 7.0
Min, Max	98, 141	-10, 19	113, 145	-5, 7	95, 136	-15, 9	95, 145	-15, 19

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hematocrit (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4	Change from baseline	N=7	Change from baseline	N=10	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	0.3400		0.3514		0.3641		0.3553	
SD	0.0583		0.0389		0.0526		0.0480	
Median	0.3610		0.3460		0.3580		0.3500	
Q1, Q3	0.3025, 0.3775		0.3140, 0.3940		0.3250, 0.4090		0.3250, 0.3830	
Min, Max	0.255, 0.383		0.310, 0.413		0.298, 0.450		0.255, 0.450	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	0.3267	-0.0100	0.3457	-0.0120	0.3633	-0.0008	0.3519	-0.0058
SD	0.0914	0.0257	0.0485	0.0103	0.0536	0.0221	0.0567	0.0194
Median	0.3530	-0.0190	0.3355	-0.0125	0.3710	0.0005	0.3540	-0.0050
Q1, Q3	0.2250, 0.4020	-0.0300, 0.0190	0.3090, 0.3910	-0.0220, -0.0030	0.3420, 0.3980	-0.0110, 0.0170	0.3090, 0.3980	-0.0220, 0.0080
Min, Max	0.225, 0.402	-0.030, 0.019	0.288, 0.415	-0.024, 0.002	0.269, 0.452	-0.040, 0.030	0.225, 0.452	-0.040, 0.030

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hematocrit (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	0.3187	-0.0180	0.3610	-0.0148	0.3340	-0.0156	0.3384	-0.0159
SD	0.0898	0.0211	0.0457	0.0249	0.0455	0.0172	0.0542	0.0187
Median	0.3520	-0.0200	0.3740	-0.0100	0.3300	-0.0160	0.3440	-0.0150
Q1, Q3	0.2170, 0.3870	-0.0380, 0.0040	0.3285, 0.3935	-0.0315, 0.0020	0.2960, 0.3810	-0.0280, - 0.0020	0.2970, 0.3870	-0.0280, - 0.0020
Min, Max	0.217, 0.387	-0.038, 0.004	0.297, 0.399	-0.049, 0.010	0.283, 0.407	-0.041, 0.011	0.217, 0.407	-0.049, 0.011
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	0.3810	0.0035	0.3615	-0.0143	0.3370	-0.0313	0.3503	-0.0214
SD	0.0212	0.0134	0.0449	0.0234	0.0567	0.0220	0.0503	0.0239
Median	0.3810	0.0035	0.3705	-0.0105	0.3050	-0.0275	0.3630	-0.0205
Q1, Q3	0.3660, 0.3960	-0.0060, 0.0130	0.3300, 0.3930	-0.0295, 0.0010	0.2970, 0.3960	-0.0460, - 0.0205	0.3000, 0.3960	-0.0400, - 0.0060
Min, Max	0.366, 0.396	-0.006, 0.013	0.300, 0.405	-0.046, 0.010	0.280, 0.420	-0.067, 0.005	0.280, 0.420	-0.067, 0.013

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hematocrit (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	0.3620	-0.0100	0.3655	-0.0103	0.3547	-0.0115	0.3593	-0.0109
SD	NC	NC	0.0372	0.0186	0.0436	0.0151	0.0374	0.0148
Median	0.3620	-0.0100	0.3765	-0.0100	0.3460	-0.0095	0.3600	-0.0100
Q1, Q3	0.3620, 0.3620	-0.0100, - 0.0100	0.3375, 0.3935	-0.0255, 0.0050	0.3400, 0.3990	-0.0220, - 0.0040	0.3400, 0.3940	-0.0220, 0.0000
Min, Max	0.362, 0.362	-0.010, -0.010	0.315, 0.394	-0.031, 0.010	0.289, 0.408	-0.034, 0.010	0.289, 0.408	-0.034, 0.010
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	0.3440	-0.0280	0.3643	-0.0115	0.3580	0.0046	0.3591	-0.0051
SD	NC	NC	0.0445	0.0246	0.0389	0.0098	0.0370	0.0193
Median	0.3440	-0.0280	0.3770	-0.0065	0.3670	0.0000	0.3635	0.0000
Q1, Q3	0.3440, 0.3440	-0.0280, - 0.0280	0.3315, 0.3970	-0.0310, 0.0080	0.3400, 0.3700	0.0000, 0.0060	0.3400, 0.3940	-0.0190, 0.0060
Min, Max	0.344, 0.344	-0.028, -0.028	0.303, 0.400	-0.043, 0.010	0.304, 0.409	-0.004, 0.021	0.303, 0.409	-0.043, 0.021

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hematocrit (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	0.3833	0.0075	0.3416	-0.0118	0.3601	-0.0032
SD	NC	NC	0.0448	0.0197	0.0541	0.0235	0.0519	0.0229
Median	NC	NC	0.3870	0.0055	0.3300	-0.0100	0.3500	-0.0040
Q1, Q3	NC, NC	NC, NC	0.3460, 0.4205	-0.0065, 0.0215	0.3040, 0.3500	-0.0240, - 0.0040	0.3300, 0.4140	-0.0140, 0.0100
Min, Max	NC, NC	NC, NC	0.332, 0.427	-0.014, 0.033	0.294, 0.430	-0.042, 0.021	0.294, 0.430	-0.042, 0.033
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	0.3890	0.0047	0.3193	-0.0200	0.3542	-0.0077
SD	NC	NC	0.0485	0.0175	0.0510	0.0464	0.0586	0.0341
Median	NC	NC	0.4160	0.0050	0.3110	0.0000	0.3535	0.0025
Q1, Q3	NC, NC	NC, NC	0.3330, 0.4180	-0.0130, 0.0220	0.2730, 0.3740	-0.0730, 0.0130	0.3110, 0.4160	-0.0130, 0.0130
Min, Max	NC, NC	NC, NC	0.333, 0.418	-0.013, 0.022	0.273, 0.374	-0.073, 0.013	0.273, 0.418	-0.073, 0.022

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hematocrit (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	0.3817	-0.0027	0.3280	-0.0080	0.3602	-0.0048
SD	NC	NC	0.0320	0.0136	0.0283	0.0255	0.0397	0.0162
Median	NC	NC	0.3960	-0.0010	0.3280	-0.0080	0.3480	-0.0010
Q1, Q3	NC, NC	NC, NC	0.3450, 0.4040	-0.0170, 0.0100	0.3080, 0.3480	-0.0260, 0.0100	0.3450, 0.3960	-0.0170, 0.0100
Min, Max	NC, NC	NC, NC	0.345, 0.404	-0.017, 0.010	0.308, 0.348	-0.026, 0.010	0.308, 0.404	-0.026, 0.010
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	0.4030	0.0090	0.3540	0.0180	0.3703	0.0150
SD	NC	NC	NC	NC	0.0269	0.0269	0.0341	0.0197
Median	NC	NC	0.4030	0.0090	0.3540	0.0180	0.3730	0.0090
Q1, Q3	NC, NC	NC, NC	0.4030, 0.4030	0.0090, 0.0090	0.3350, 0.3730	-0.0010, 0.0370	0.3350, 0.4030	-0.0010, 0.0370
Min, Max	NC, NC	NC, NC	0.403, 0.403	0.009, 0.009	0.335, 0.373	-0.001, 0.037	0.335, 0.403	-0.001, 0.037

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hematocrit (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.4220	0.0280	0.3380	0.0400	0.3800	0.0340
SD	NC	NC	NC	NC	NC	NC	0.0594	0.0085
Median	NC	NC	0.4220	0.0280	0.3380	0.0400	0.3800	0.0340
Q1, Q3	NC, NC	NC, NC	0.4220, 0.4220	0.0280, 0.0280	0.3380, 0.3380	0.0400, 0.0400	0.3380, 0.4220	0.0280, 0.0400
Min, Max	NC, NC	NC, NC	0.422, 0.422	0.028, 0.028	0.338, 0.338	0.040, 0.040	0.338, 0.422	0.028, 0.040
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.4300	0.0360	0.3120	0.0140	0.3710	0.0250
SD	NC	NC	NC	NC	NC	NC	0.0834	0.0156
Median	NC	NC	0.4300	0.0360	0.3120	0.0140	0.3710	0.0250
Q1, Q3	NC, NC	NC, NC	0.4300, 0.4300	0.0360, 0.0360	0.3120, 0.3120	0.0140, 0.0140	0.3120, 0.4300	0.0140, 0.0360
Min, Max	NC, NC	NC, NC	0.430, 0.430	0.036, 0.036	0.312, 0.312	0.014, 0.014	0.312, 0.430	0.014, 0.036

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hematocrit (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.4510	0.0570	0.3330	0.0350	0.3920	0.0460
SD	NC	NC	NC	NC	NC	NC	0.0834	0.0156
Median	NC	NC	0.4510	0.0570	0.3330	0.0350	0.3920	0.0460
Q1, Q3	NC, NC	NC, NC	0.4510, 0.4510	0.0570, 0.0570	0.3330, 0.3330	0.0350, 0.0350	0.3330, 0.4510	0.0350, 0.0570
Min, Max	NC, NC	NC, NC	0.451, 0.451	0.057, 0.057	0.333, 0.333	0.035, 0.035	0.333, 0.451	0.035, 0.057
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.4250	0.0310	NC	NC	0.4250	0.0310
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.4250	0.0310	NC	NC	0.4250	0.0310
Q1, Q3	NC, NC	NC, NC	0.4250, 0.4250	0.0310, 0.0310	NC, NC	NC, NC	0.4250, 0.4250	0.0310, 0.0310
Min, Max	NC, NC	NC, NC	0.425, 0.425	0.031, 0.031	NC, NC	NC, NC	0.425, 0.425	0.031, 0.031

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hematocrit (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.4060	0.0120	NC	NC	0.4060	0.0120
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.4060	0.0120	NC	NC	0.4060	0.0120
Q1, Q3	NC, NC	NC, NC	0.4060, 0.4060	0.0120, 0.0120	NC, NC	NC, NC	0.4060, 0.4060	0.0120, 0.0120
Min, Max	NC, NC	NC, NC	0.406, 0.406	0.012, 0.012	NC, NC	NC, NC	0.406, 0.406	0.012, 0.012
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.1470	-0.2470	NC	NC	0.1470	-0.2470
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.1470	-0.2470	NC	NC	0.1470	-0.2470
Q1, Q3	NC, NC	NC, NC	0.1470, 0.1470	-0.2470, - 0.2470	NC, NC	NC, NC	0.1470, 0.1470	-0.2470, - 0.2470
Min, Max	NC, NC	NC, NC	0.147, 0.147	-0.247, -0.247	NC, NC	NC, NC	0.147, 0.147	-0.247, -0.247

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Hematocrit (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	0.3630	0.0263	0.3775	0.0018	0.3414	-0.0138	0.3553	-0.0016
SD	0.0637	0.0471	0.0367	0.0198	0.0316	0.0320	0.0404	0.0342
Median	0.3440	0.0510	0.3715	-0.0005	0.3355	-0.0120	0.3440	-0.0010
Q1, Q3	0.3110, 0.4340	-0.0280, 0.0560	0.3475, 0.4075	-0.0105, 0.0140	0.3215, 0.3595	-0.0325, 0.0070	0.3330, 0.3930	-0.0280, 0.0280
Min, Max	0.311, 0.434	-0.028, 0.056	0.345, 0.422	-0.020, 0.028	0.303, 0.395	-0.070, 0.035	0.303, 0.434	-0.070, 0.056

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Volume (fL)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	88.00		87.86		88.89		88.38	
SD	2.828		5.786		6.346		5.443	
Median	87.00		88.00		89.00		88.00	
Q1, Q3	86.00, 90.00		81.00, 95.00		86.00, 93.00		86.00, 92.00	
Min, Max	86.0, 92.0		81.0, 95.0		78.0, 99.0		78.0, 99.0	
Cycle 1 Day 6								
Nx	2	2	6	6	10	10	18	18
Mean	89.50	-0.50	87.17	-0.50	89.71	0.82	88.84	0.23
SD	3.536	0.707	7.026	1.871	6.126	0.925	6.050	1.403
Median	89.50	-0.50	85.50	-0.50	90.00	1.00	89.00	0.55
Q1, Q3	87.00, 92.00	-1.00, 0.00	83.00, 95.00	-2.00, 1.00	87.00, 94.00	0.10, 1.00	85.00, 94.00	-1.00, 1.00
Min, Max	87.0, 92.0	-1.0, 0.0	78.0, 96.0	-3.0, 2.0	78.1, 100.0	-1.0, 2.1	78.0, 100.0	-3.0, 2.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Volume (fL)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	2	2	4	4	7	7	13	13
Mean	89.50	-0.50	90.50	0.75	89.74	-0.24	89.94	0.02
SD	3.536	0.707	6.608	1.500	5.916	0.529	5.442	1.003
Median	89.50	-0.50	91.00	1.00	90.00	0.00	90.00	0.00
Q1, Q3	87.00, 92.00	-1.00, 0.00	85.00, 96.00	-0.50, 2.00	86.00, 94.00	-1.00, 0.00	86.00, 94.00	-1.00, 0.00
Min, Max	87.0, 92.0	-1.0, 0.0	83.0, 97.0	-1.0, 2.0	81.2, 99.0	-1.0, 0.3	81.2, 99.0	-1.0, 2.0
Cycle 2 Day 1								
Nx	1	1	4	4	8	8	13	13
Mean	92.00	0.00	90.75	1.00	88.58	-0.16	89.51	0.21
SD	NC	NC	6.946	1.826	6.716	1.529	6.323	1.581
Median	92.00	0.00	91.00	1.00	89.50	0.30	91.00	0.00
Q1, Q3	92.00, 92.00	0.00, 0.00	85.00, 96.50	-0.50, 2.50	83.50, 92.00	-1.00, 1.00	85.00, 92.00	0.00, 1.00
Min, Max	92.0, 92.0	0.0, 0.0	83.0, 98.0	-1.0, 3.0	78.6, 100.0	-3.0, 1.1	78.6, 100.0	-3.0, 3.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Volume (fL)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	82.00	-4.00	89.75	0.00	90.87	0.05	89.65	-0.34
SD	NC	NC	6.021	0.816	5.895	3.075	5.915	2.531
Median	82.00	-4.00	91.00	0.00	89.50	1.00	89.00	0.00
Q1, Q3	82.00, 82.00	-4.00, -4.00	85.00, 94.50	-0.50, 0.50	89.00, 93.00	0.00, 2.00	83.20, 94.00	-1.00, 1.00
Min, Max	82.0, 82.0	-4.0, -4.0	82.0, 95.0	-1.0, 1.0	83.2, 101.0	-6.0, 2.3	82.0, 101.0	-6.0, 2.3
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	79.00	-7.00	90.25	0.50	91.56	1.58	89.78	0.29
SD	NC	NC	6.292	1.291	6.940	1.132	7.027	2.824
Median	79.00	-7.00	91.00	0.50	90.00	1.90	90.00	1.00
Q1, Q3	79.00, 79.00	-7.00, -7.00	85.00, 95.50	-0.50, 1.50	90.00, 93.00	1.00, 2.00	83.00, 95.00	0.00, 2.00
Min, Max	79.0, 79.0	-7.0, -7.0	83.0, 96.0	-1.0, 2.0	82.8, 102.0	0.0, 3.0	79.0, 102.0	-7.0, 3.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Volume (fL)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	90.25	0.50	90.34	0.36	90.30	0.42
SD	NC	NC	5.620	1.732	7.588	2.061	6.375	1.804
Median	NC	NC	91.00	1.00	90.00	0.80	90.00	1.00
Q1, Q3	NC, NC	NC, NC	86.00, 94.50	-0.50, 1.50	85.00, 94.00	0.00, 2.00	85.00, 94.00	0.00, 2.00
Min, Max	NC, NC	NC, NC	83.0, 96.0	-2.0, 2.0	81.7, 101.0	-3.0, 2.0	81.7, 101.0	-3.0, 2.0
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	91.33	1.00	91.00	-1.33	91.17	-0.17
SD	NC	NC	8.083	0.000	7.000	1.155	6.765	1.472
Median	NC	NC	96.00	1.00	88.00	-2.00	92.00	0.50
Q1, Q3	NC, NC	NC, NC	82.00, 96.00	1.00, 1.00	86.00, 99.00	-2.00, 0.00	86.00, 96.00	-2.00, 1.00
Min, Max	NC, NC	NC, NC	82.0, 96.0	1.0, 1.0	86.0, 99.0	-2.0, 0.0	82.0, 99.0	-2.0, 1.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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(Safety Set)

Parameter: Ery. Mean Corpuscular Volume (fL)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	89.67	-0.67	86.50	-2.50	88.40	-1.40
SD	NC	NC	8.505	1.528	3.536	2.121	6.504	1.817
Median	NC	NC	93.00	-1.00	86.50	-2.50	89.00	-1.00
Q1, Q3	NC, NC	NC, NC	80.00, 96.00	-2.00, 1.00	84.00, 89.00	-4.00, -1.00	84.00, 93.00	-2.00, -1.00
Min, Max	NC, NC	NC, NC	80.0, 96.0	-2.0, 1.0	84.0, 89.0	-4.0, -1.0	80.0, 96.0	-4.0, 1.0
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	93.00	-2.00	86.50	-2.50	88.67	-2.33
SD	NC	NC	NC	NC	2.121	0.707	4.041	0.577
Median	NC	NC	93.00	-2.00	86.50	-2.50	88.00	-2.00
Q1, Q3	NC, NC	NC, NC	93.00, 93.00	-2.00, -2.00	85.00, 88.00	-3.00, -2.00	85.00, 93.00	-3.00, -2.00
Min, Max	NC, NC	NC, NC	93.0, 93.0	-2.0, -2.0	85.0, 88.0	-3.0, -2.0	85.0, 93.0	-3.0, -2.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Parameter: Ery. Mean Corpuscular Volume (fL)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	97.00	2.00	88.00	-2.00	92.50	0.00
SD	NC	NC	NC	NC	NC	NC	6.364	2.828
Median	NC	NC	97.00	2.00	88.00	-2.00	92.50	0.00
Q1, Q3	NC, NC	NC, NC	97.00, 97.00	2.00, 2.00	88.00, 88.00	-2.00, -2.00	88.00, 97.00	-2.00, 2.00
Min, Max	NC, NC	NC, NC	97.0, 97.0	2.0, 2.0	88.0, 88.0	-2.0, -2.0	88.0, 97.0	-2.0, 2.0
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	97.00	2.00	88.00	-2.00	92.50	0.00
SD	NC	NC	NC	NC	NC	NC	6.364	2.828
Median	NC	NC	97.00	2.00	88.00	-2.00	92.50	0.00
Q1, Q3	NC, NC	NC, NC	97.00, 97.00	2.00, 2.00	88.00, 88.00	-2.00, -2.00	88.00, 97.00	-2.00, 2.00
Min, Max	NC, NC	NC, NC	97.0, 97.0	2.0, 2.0	88.0, 88.0	-2.0, -2.0	88.0, 97.0	-2.0, 2.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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(Safety Set)

Parameter: Ery. Mean Corpuscular Volume (fL)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	96.00	1.00	90.00	0.00	93.00	0.50
SD	NC	NC	NC	NC	NC	NC	4.243	0.707
Median	NC	NC	96.00	1.00	90.00	0.00	93.00	0.50
Q1, Q3	NC, NC	NC, NC	96.00, 96.00	1.00, 1.00	90.00, 90.00	0.00, 0.00	90.00, 96.00	0.00, 1.00
Min, Max	NC, NC	NC, NC	96.0, 96.0	1.0, 1.0	90.0, 90.0	0.0, 0.0	90.0, 96.0	0.0, 1.0
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	97.00	2.00	NC	NC	97.00	2.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	97.00	2.00	NC	NC	97.00	2.00
Q1, Q3	NC, NC	NC, NC	97.00, 97.00	2.00, 2.00	NC, NC	NC, NC	97.00, 97.00	2.00, 2.00
Min, Max	NC, NC	NC, NC	97.0, 97.0	2.0, 2.0	NC, NC	NC, NC	97.0, 97.0	2.0, 2.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Volume (fL)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	96.00	1.00	NC	NC	96.00	1.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	96.00	1.00	NC	NC	96.00	1.00
Q1, Q3	NC, NC	NC, NC	96.00, 96.00	1.00, 1.00	NC, NC	NC, NC	96.00, 96.00	1.00, 1.00
Min, Max	NC, NC	NC, NC	96.0, 96.0	1.0, 1.0	NC, NC	NC, NC	96.0, 96.0	1.0, 1.0
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	96.00	1.00	NC	NC	96.00	1.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	96.00	1.00	NC	NC	96.00	1.00
Q1, Q3	NC, NC	NC, NC	96.00, 96.00	1.00, 1.00	NC, NC	NC, NC	96.00, 96.00	1.00, 1.00
Min, Max	NC, NC	NC, NC	96.0, 96.0	1.0, 1.0	NC, NC	NC, NC	96.0, 96.0	1.0, 1.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Volume (fL)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	87.67	-1.00	90.25	0.50	86.71	-0.90	87.85	-0.55
SD	7.572	5.292	8.057	1.915	7.670	1.701	7.342	2.581
Median	91.00	1.00	91.50	1.00	86.00	-0.85	87.00	0.00
Q1, Q3	79.00, 93.00	-7.00, 3.00	83.50, 97.00	-1.00, 2.00	81.60, 91.50	-1.75, 0.50	81.00, 93.00	-2.00, 1.00
Min, Max	79.0, 93.0	-7.0, 3.0	81.0, 97.0	-2.0, 2.0	75.5, 100.0	-4.0, 1.0	75.5, 100.0	-7.0, 3.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value			Value		Value		Value	
Baseline								
Nx	4		7		10		21	
Mean	126.82		213.79		205.57		193.31	
SD	195.769		233.823		229.032		216.476	
Median	29.20		30.70		31.80		30.70	
Q1, Q3	28.70, 224.94		28.40, 438.19		29.60, 460.75		28.80, 431.75	
Min, Max	28.4, 420.5		28.0, 536.5		24.0, 504.2		24.0, 536.5	
Cycle 1 Day 6								
Nx	2	2	6	6	10	10	18	18
Mean	28.95	-0.25	243.28	-1.34	206.28	0.71	198.91	-0.08
SD	1.202	0.919	237.823	4.956	229.871	1.561	220.760	3.082
Median	28.95	-0.25	219.14	0.40	32.05	0.15	31.05	0.15
Q1, Q3	28.10, 29.80	-0.90, 0.40	29.20, 439.80	-0.80, 1.61	29.60, 463.97	-0.10, 1.61	29.20, 439.80	-0.40, 1.61
Min, Max	28.1, 29.8	-0.9, 0.4	27.2, 525.2	-11.3, 1.6	24.0, 505.9	-1.6, 3.2	24.0, 525.2	-11.3, 3.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	2	2	4	4	7	7	13	13
Mean	28.90	-0.30	258.89	0.45	218.18	-1.86	201.58	-0.91
SD	1.273	0.990	266.582	8.561	236.383	2.998	227.882	4.909
Median	28.90	-0.30	240.03	0.10	32.10	-0.20	31.60	-0.20
Q1, Q3	28.00, 29.80	-1.00, 0.40	29.65, 488.13	-4.88, 5.79	29.40, 478.47	-3.22, 0.00	29.40, 449.47	-1.61, 0.30
Min, Max	28.0, 29.8	-1.0, 0.4	28.7, 526.8	-9.7, 11.3	24.5, 501.0	-8.1, 0.3	24.5, 526.8	-9.7, 11.3
Cycle 2 Day 1								
Nx	1	1	4	4	8	8	13	13
Mean	32.80	3.40	257.81	-0.63	246.68	-2.74	233.65	-1.62
SD	NC	NC	267.027	0.700	234.259	7.488	231.316	6.008
Median	32.80	3.40	234.30	-0.45	230.66	-0.10	32.80	-0.20
Q1, Q3	32.80, 32.80	3.40, 3.40	29.10, 486.52	-1.11, -0.15	28.05, 472.83	-1.76, 0.55	30.40, 462.36	-0.60, 0.10
Min, Max	32.8, 32.8	3.4, 3.4	27.8, 534.9	-1.6, 0.0	23.8, 486.5	-20.9, 1.6	23.8, 534.9	-20.9, 3.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	393.08	-27.39	259.72	1.28	243.78	-12.83	263.15	-9.02
SD	NC	NC	267.972	4.788	233.714	19.123	225.326	16.571
Median	393.08	-27.39	238.47	0.15	240.22	-3.22	393.08	0.00
Q1, Q3	393.08, 393.08	-27.39, -27.39	29.70, 489.74	-1.61, 4.18	33.00, 454.30	-33.83, 1.20	30.70, 454.30	-27.39, 1.20
Min, Max	393.1, 393.1	-27.4, -27.4	28.7, 533.2	-3.2, 8.1	24.5, 470.4	-40.3, 2.4	24.5, 533.2	-40.3, 8.1
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	380.20	-40.28	259.37	0.93	202.28	-4.80	242.91	-6.05
SD	NC	NC	267.911	1.537	236.066	7.763	227.651	13.426
Median	380.20	-40.28	236.26	0.25	33.40	-0.40	206.80	0.05
Q1, Q3	380.20, 380.20	-40.28, -40.28	29.80, 488.94	0.05, 1.81	31.40, 451.08	-9.67, 0.60	31.10, 451.08	-9.67, 0.60
Min, Max	380.2, 380.2	-40.3, -40.3	28.5, 536.5	0.0, 3.2	25.1, 470.4	-16.1, 1.6	25.1, 536.5	-40.3, 3.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	256.83	-1.61	202.72	-4.35	226.77	-3.13
SD	NC	NC	265.104	3.223	237.164	6.431	235.142	5.163
Median	NC	NC	234.50	-0.05	32.40	-0.20	32.40	-0.10
Q1, Q3	NC, NC	NC, NC	29.55, 484.11	-3.27, 0.05	31.60, 451.08	-9.67, 0.40	30.80, 451.08	-6.44, 0.10
Min, Max	NC, NC	NC, NC	28.3, 530.0	-6.4, 0.1	24.9, 473.6	-12.9, 0.6	24.9, 530.0	-12.9, 0.6
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	334.61	-0.50	314.11	-12.25	324.36	-6.38
SD	NC	NC	266.424	7.268	244.522	10.899	228.988	10.490
Median	NC	NC	444.64	0.10	443.03	-17.72	443.83	-3.98
Q1, Q3	NC, NC	NC, NC	30.80, 528.41	-8.06, 6.44	32.10, 467.19	-19.33, 0.30	32.10, 467.19	-17.72, 0.30
Min, Max	NC, NC	NC, NC	30.8, 528.4	-8.1, 6.4	32.1, 467.2	-19.3, 0.3	30.8, 528.4	-19.3, 6.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	334.68	-0.44	451.89	-21.75	381.56	-8.96
SD	NC	NC	266.310	7.278	14.809	3.417	199.089	12.871
Median	NC	NC	444.64	0.30	451.89	-21.75	444.64	-8.06
Q1, Q3	NC, NC	NC, NC	31.00, 528.41	-8.06, 6.44	441.41, 462.36	-24.17, -19.33	441.41, 462.36	-19.33, 0.30
Min, Max	NC, NC	NC, NC	31.0, 528.4	-8.1, 6.4	441.4, 462.4	-24.2, -19.3	31.0, 528.4	-24.2, 6.4
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	534.85	-1.61	463.97	-9.67	487.60	-6.98
SD	NC	NC	NC	NC	9.113	9.113	41.429	7.947
Median	NC	NC	534.85	-1.61	463.97	-9.67	470.41	-3.22
Q1, Q3	NC, NC	NC, NC	534.85, 534.85	-1.61, -1.61	457.52, 470.41	-16.11, -3.22	457.52, 534.85	-16.11, -1.61
Min, Max	NC, NC	NC, NC	534.9, 534.9	-1.6, -1.6	457.5, 470.4	-16.1, -3.2	457.5, 534.9	-16.1, -1.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	534.85	-1.61	470.41	-16.11	502.63	-8.86
SD	NC	NC	NC	NC	NC	NC	45.566	10.252
Median	NC	NC	534.85	-1.61	470.41	-16.11	502.63	-8.86
Q1, Q3	NC, NC	NC, NC	534.85, 534.85	-1.61, -1.61	470.41, 470.41	-16.11, -16.11	470.41, 534.85	-16.11, -1.61
Min, Max	NC, NC	NC, NC	534.9, 534.9	-1.6, -1.6	470.4, 470.4	-16.1, -16.1	470.4, 534.9	-16.1, -1.6
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	534.85	-1.61	475.25	-11.28	505.05	-6.44
SD	NC	NC	NC	NC	NC	NC	42.149	6.835
Median	NC	NC	534.85	-1.61	475.25	-11.28	505.05	-6.44
Q1, Q3	NC, NC	NC, NC	534.85, 534.85	-1.61, -1.61	475.25, 475.25	-11.28, -11.28	475.25, 534.85	-11.28, -1.61
Min, Max	NC, NC	NC, NC	534.9, 534.9	-1.6, -1.6	475.2, 475.2	-11.3, -11.3	475.2, 534.9	-11.3, -1.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	533.24	-3.22	473.63	-12.89	503.44	-8.06
SD	NC	NC	NC	NC	NC	NC	42.149	6.835
Median	NC	NC	533.24	-3.22	473.63	-12.89	503.44	-8.06
Q1, Q3	NC, NC	NC, NC	533.24, 533.24	-3.22, -3.22	473.63, 473.63	-12.89, -12.89	473.63, 533.24	-12.89, -3.22
Min, Max	NC, NC	NC, NC	533.2, 533.2	-3.2, -3.2	473.6, 473.6	-12.9, -12.9	473.6, 533.2	-12.9, -3.2
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	536.46	0.00	NC	NC	536.46	0.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	536.46	0.00	NC	NC	536.46	0.00
Q1, Q3	NC, NC	NC, NC	536.46, 536.46	0.00, 0.00	NC, NC	NC, NC	536.46, 536.46	0.00, 0.00
Min, Max	NC, NC	NC, NC	536.5, 536.5	0.0, 0.0	NC, NC	NC, NC	536.5, 536.5	0.0, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	530.02	-6.44	NC	NC	530.02	-6.44
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	530.02	-6.44	NC	NC	530.02	-6.44
Q1, Q3	NC, NC	NC, NC	530.02, 530.02	-6.44, -6.44	NC, NC	NC, NC	530.02, 530.02	-6.44, -6.44
Min, Max	NC, NC	NC, NC	530.0, 530.0	-6.4, -6.4	NC, NC	NC, NC	530.0, 530.0	-6.4, -6.4
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	536.46	0.00	NC	NC	536.46	0.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	536.46	0.00	NC	NC	536.46	0.00
Q1, Q3	NC, NC	NC, NC	536.46, 536.46	0.00, 0.00	NC, NC	NC, NC	536.46, 536.46	0.00, 0.00
Min, Max	NC, NC	NC, NC	536.5, 536.5	0.0, 0.0	NC, NC	NC, NC	536.5, 536.5	0.0, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Ery. Mean Corpuscular Hemoglobin (pg)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	148.10	-11.53	260.73	2.29	187.55	-2.54	199.17	-3.05
SD	201.003	24.899	268.844	3.870	220.601	6.836	217.510	11.783
Median	32.50	2.60	238.97	0.55	31.70	-0.10	32.00	0.20
Q1, Q3	31.60, 380.20	-40.28, 3.10	30.10, 491.36	0.05, 4.53	26.50, 443.03	-7.44, 0.60	28.50, 446.25	-2.00, 2.60
Min, Max	31.6, 380.2	-40.3, 3.1	28.5, 536.5	0.0, 8.1	24.3, 473.6	-12.9, 6.4	24.3, 536.5	-40.3, 8.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Reticulocytes/Erythrocytes (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value			Value		Value		Value	
Baseline								
Nx	0		3		1		4	
Mean	NC		0.0150		0.0220		0.0168	
SD	NC		0.0066		NC		0.0064	
Median	NC		0.0140		0.0220		0.0180	
Q1, Q3	NC, NC		0.0090, 0.0220		0.0220, 0.0220		0.0115, 0.0220	
Min, Max	NC, NC		0.0090, 0.0220		0.0220, 0.0220		0.0090, 0.0220	
Cycle 1 Day 6								
Nx	1	0	0	0	1	0	2	0
Mean	0.4630	NC	NC	NC	0.0060	NC	0.2345	NC
SD	NC	NC	NC	NC	NC	NC	0.3231	NC
Median	0.4630	NC	NC	NC	0.0060	NC	0.2345	NC
Q1, Q3	0.4630, 0.4630	NC, NC	NC, NC	NC, NC	0.0060, 0.0060	NC, NC	0.0060, 0.4630	NC, NC
Min, Max	0.4630, 0.4630	NC, NC	NC, NC	NC, NC	0.0060, 0.0060	NC, NC	0.0060, 0.4630	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Reticulocytes/Erythrocytes (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	1	0	0	0	0	0	1	0
Mean	0.5470	NC	NC	NC	NC	NC	0.5470	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	0.5470	NC	NC	NC	NC	NC	0.5470	NC
Q1, Q3	0.5470, 0.5470	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC	0.5470, 0.5470	NC, NC
Min, Max	0.5470, 0.5470	NC, NC	NC, NC	NC, NC	NC, NC	NC, NC	0.5470, 0.5470	NC, NC
Cycle 2 Day 1								
Nx	0	0	0	0	2	0	2	0
Mean	NC	NC	NC	NC	0.0140	NC	0.0140	NC
SD	NC	NC	NC	NC	0.0042	NC	0.0042	NC
Median	NC	NC	NC	NC	0.0140	NC	0.0140	NC
Q1, Q3	NC, NC	NC, NC	NC, NC	NC, NC	0.0110, 0.0170	NC, NC	0.0110, 0.0170	NC, NC
Min, Max	NC, NC	NC, NC	NC, NC	NC, NC	0.0110, 0.0170	NC, NC	0.0110, 0.0170	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Reticulocytes/Erythrocytes (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	0	0	1	0	1	0	2	0
Mean	NC	NC	0.6300	NC	0.0120	NC	0.3210	NC
SD	NC	NC	NC	NC	NC	NC	0.4370	NC
Median	NC	NC	0.6300	NC	0.0120	NC	0.3210	NC
Q1, Q3	NC, NC	NC, NC	0.6300, 0.6300	NC, NC	0.0120, 0.0120	NC, NC	0.0120, 0.6300	NC, NC
Min, Max	NC, NC	NC, NC	0.6300, 0.6300	NC, NC	0.0120, 0.0120	NC, NC	0.0120, 0.6300	NC, NC
Cycle 5 Day 1								
Nx	0	0	1	0	1	0	2	0
Mean	NC	NC	0.0195	NC	0.0140	NC	0.0168	NC
SD	NC	NC	NC	NC	NC	NC	0.0039	NC
Median	NC	NC	0.0195	NC	0.0140	NC	0.0168	NC
Q1, Q3	NC, NC	NC, NC	0.0195, 0.0195	NC, NC	0.0140, 0.0140	NC, NC	0.0140, 0.0195	NC, NC
Min, Max	NC, NC	NC, NC	0.0195, 0.0195	NC, NC	0.0140, 0.0140	NC, NC	0.0140, 0.0195	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Reticulocytes/Erythrocytes (fraction of 1)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	1	0	1	0	2	0
Mean	NC	NC	0.0152	NC	0.0150	NC	0.0151	NC
SD	NC	NC	NC	NC	NC	NC	0.0001	NC
Median	NC	NC	0.0152	NC	0.0150	NC	0.0151	NC
Q1, Q3	NC, NC	NC, NC	0.0152, 0.0152	NC, NC	0.0150, 0.0150	NC, NC	0.0150, 0.0152	NC, NC
Min, Max	NC, NC	NC, NC	0.0152, 0.0152	NC, NC	0.0150, 0.0150	NC, NC	0.0150, 0.0152	NC, NC
End of Treatment								
Nx	0	0	1	0	2	0	3	0
Mean	NC	NC	0.0142	NC	0.0140	NC	0.0141	NC
SD	NC	NC	NC	NC	0.0000	NC	0.0001	NC
Median	NC	NC	0.0142	NC	0.0140	NC	0.0140	NC
Q1, Q3	NC, NC	NC, NC	0.0142, 0.0142	NC, NC	0.0140, 0.0140	NC, NC	0.0140, 0.0142	NC, NC
Min, Max	NC, NC	NC, NC	0.0142, 0.0142	NC, NC	0.0140, 0.0140	NC, NC	0.0140, 0.0142	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Leukocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	5.525		6.314		8.072		7.001	
SD	1.4315		2.9180		3.3826		3.0307	
Median	5.350		6.700		7.300		6.700	
Q1, Q3	4.500, 6.550		3.300, 9.000		5.300, 9.840		5.000, 8.700	
Min, Max	4.00, 7.40		2.90, 9.70		4.00, 14.18		2.90, 14.18	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	6.500	1.033	5.450	-0.300	7.749	-0.323	6.826	-0.102
SD	2.9866	1.8148	3.3875	0.8270	3.0466	1.5185	3.1531	1.4014
Median	7.700	1.300	4.450	-0.650	7.450	-0.750	7.300	-0.600
Q1, Q3	3.100, 8.700	-0.900, 2.700	2.400, 9.100	-0.900, 0.100	6.100, 10.000	-1.500, 0.900	3.100, 9.100	-0.900, 1.200
Min, Max	3.10, 8.70	-0.90, 2.70	2.40, 9.90	-0.90, 1.20	3.10, 12.98	-2.20, 2.40	2.40, 12.98	-2.20, 2.70

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Leukocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	5.767	0.300	3.250	-0.950	6.286	-1.569	5.307	-0.991
SD	2.8572	1.3000	1.2974	0.4796	3.7311	1.7258	3.1522	1.5008
Median	6.000	1.000	2.800	-0.850	4.500	-1.100	4.350	-0.950
Q1, Q3	2.800, 8.500	-1.200, 1.100	2.350, 4.150	-1.300, -0.600	3.900, 9.500	-2.500, 0.200	3.100, 6.000	-1.600, 0.200
Min, Max	2.80, 8.50	-1.20, 1.10	2.30, 5.10	-1.60, -0.50	3.10, 13.30	-4.68, 0.20	2.30, 13.30	-4.68, 1.10
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	5.250	0.750	3.775	-0.425	5.806	-2.671	5.146	-1.541
SD	2.3335	1.6263	2.7134	1.0243	2.3676	2.0462	2.4463	2.1626
Median	5.250	0.750	2.600	-0.850	4.850	-1.850	4.350	-1.000
Q1, Q3	3.600, 6.900	-0.400, 1.900	2.150, 5.400	-1.000, 0.150	4.200, 8.270	-4.200, -1.015	3.000, 7.740	-1.900, -0.800
Min, Max	3.60, 6.90	-0.40, 1.90	2.10, 7.80	-1.10, 1.10	2.80, 9.01	-6.44, -0.80	2.10, 9.01	-6.44, 1.90

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Leukocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	7.500	2.500	3.550	-0.650	7.448	-1.548	6.035	-0.854
SD	NC	NC	1.5460	0.2082	2.7369	1.1534	2.8889	1.4523
Median	7.500	2.500	3.050	-0.650	6.200	-1.700	5.800	-0.700
Q1, Q3	7.500, 7.500	2.500, 2.500	2.600, 4.500	-0.800, -0.500	5.500, 10.300	-2.690, -0.300	3.200, 7.500	-1.900, -0.300
Min, Max	7.50, 7.50	2.50, 2.50	2.30, 5.80	-0.90, -0.40	5.00, 11.49	-2.80, -0.10	2.30, 11.49	-2.80, 2.50
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	6.500	1.500	3.475	-0.725	7.712	-0.464	5.896	-0.372
SD	NC	NC	1.4546	0.2630	4.4102	1.6551	3.7185	1.3000
Median	6.500	1.500	2.950	-0.650	5.900	0.100	5.750	-0.550
Q1, Q3	6.500, 6.500	1.500, 1.500	2.550, 4.400	-0.900, -0.550	5.900, 6.200	-2.000, 0.600	3.200, 6.200	-1.100, 0.600
Min, Max	6.50, 6.50	1.50, 1.50	2.40, 5.60	-1.10, -0.50	5.00, 15.56	-2.40, 1.38	2.40, 15.56	-2.40, 1.50

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Leukocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	3.850	-0.350	7.908	-0.268	6.104	-0.304
SD	NC	NC	1.5264	0.4123	5.4394	2.2372	4.4991	1.6026
Median	NC	NC	3.500	-0.400	6.200	-0.800	5.000	-0.400
Q1, Q3	NC, NC	NC, NC	2.700, 5.000	-0.600, -0.100	5.000, 6.300	-2.000, 0.200	4.100, 6.200	-0.800, 0.200
Min, Max	NC, NC	NC, NC	2.50, 5.90	-0.80, 0.20	4.50, 17.54	-2.10, 3.36	2.50, 17.54	-2.10, 3.36
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	3.500	-0.800	6.633	0.067	5.067	-0.367
SD	NC	NC	1.7776	0.4000	1.8771	2.7574	2.3704	1.8250
Median	NC	NC	2.900	-0.800	5.600	0.300	5.500	-0.600
Q1, Q3	NC, NC	NC, NC	2.100, 5.500	-1.200, -0.400	5.500, 8.800	-2.800, 2.700	2.900, 5.600	-1.200, 0.300
Min, Max	NC, NC	NC, NC	2.10, 5.50	-1.20, -0.40	5.50, 8.80	-2.80, 2.70	2.10, 8.80	-2.80, 2.70

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Leukocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	4.033	-0.267	5.100	-1.700	4.460	-0.840
SD	NC	NC	2.2502	0.2082	0.0000	2.1213	1.6950	1.3278
Median	NC	NC	3.100	-0.200	5.100	-1.700	5.100	-0.200
Q1, Q3	NC, NC	NC, NC	2.400, 6.600	-0.500, -0.100	5.100, 5.100	-3.200, -0.200	3.100, 5.100	-0.500, -0.200
Min, Max	NC, NC	NC, NC	2.40, 6.60	-0.50, -0.10	5.10, 5.10	-3.20, -0.20	2.40, 6.60	-3.20, -0.10
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	3.000	-0.300	5.900	-0.900	4.933	-0.700
SD	NC	NC	NC	NC	0.7071	1.4142	1.7474	1.0583
Median	NC	NC	3.000	-0.300	5.900	-0.900	5.400	-0.300
Q1, Q3	NC, NC	NC, NC	3.000, 3.000	-0.300, -0.300	5.400, 6.400	-1.900, 0.100	3.000, 6.400	-1.900, 0.100
Min, Max	NC, NC	NC, NC	3.00, 3.00	-0.30, -0.30	5.40, 6.40	-1.90, 0.10	3.00, 6.40	-1.90, 0.10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Leukocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	2.900	-0.400	4.900	-0.400	3.900	-0.400
SD	NC	NC	NC	NC	NC	NC	1.4142	0.0000
Median	NC	NC	2.900	-0.400	4.900	-0.400	3.900	-0.400
Q1, Q3	NC, NC	NC, NC	2.900, 2.900	-0.400, -0.400	4.900, 4.900	-0.400, -0.400	2.900, 4.900	-0.400, -0.400
Min, Max	NC, NC	NC, NC	2.90, 2.90	-0.40, -0.40	4.90, 4.90	-0.40, -0.40	2.90, 4.90	-0.40, -0.40
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	3.300	0.000	4.700	-0.600	4.000	-0.300
SD	NC	NC	NC	NC	NC	NC	0.9899	0.4243
Median	NC	NC	3.300	0.000	4.700	-0.600	4.000	-0.300
Q1, Q3	NC, NC	NC, NC	3.300, 3.300	0.000, 0.000	4.700, 4.700	-0.600, -0.600	3.300, 4.700	-0.600, 0.000
Min, Max	NC, NC	NC, NC	3.30, 3.30	0.00, 0.00	4.70, 4.70	-0.60, -0.60	3.30, 4.70	-0.60, 0.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Leukocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	7.900	4.600	4.800	-0.500	6.350	2.050
SD	NC	NC	NC	NC	NC	NC	2.1920	3.6062
Median	NC	NC	7.900	4.600	4.800	-0.500	6.350	2.050
Q1, Q3	NC, NC	NC, NC	7.900, 7.900	4.600, 4.600	4.800, 4.800	-0.500, -0.500	4.800, 7.900	-0.500, 4.600
Min, Max	NC, NC	NC, NC	7.90, 7.90	4.60, 4.60	4.80, 4.80	-0.50, -0.50	4.80, 7.90	-0.50, 4.60
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	3.700	0.400	NC	NC	3.700	0.400
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	3.700	0.400	NC	NC	3.700	0.400
Q1, Q3	NC, NC	NC, NC	3.700, 3.700	0.400, 0.400	NC, NC	NC, NC	3.700, 3.700	0.400, 0.400
Min, Max	NC, NC	NC, NC	3.70, 3.70	0.40, 0.40	NC, NC	NC, NC	3.70, 3.70	0.40, 0.40

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Leukocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.100	0.800	NC	NC	4.100	0.800
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.100	0.800	NC	NC	4.100	0.800
Q1, Q3	NC, NC	NC, NC	4.100, 4.100	0.800, 0.800	NC, NC	NC, NC	4.100, 4.100	0.800, 0.800
Min, Max	NC, NC	NC, NC	4.10, 4.10	0.80, 0.80	NC, NC	NC, NC	4.10, 4.10	0.80, 0.80
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	3.400	0.100	NC	NC	3.400	0.100
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	3.400	0.100	NC	NC	3.400	0.100
Q1, Q3	NC, NC	NC, NC	3.400, 3.400	0.100, 0.100	NC, NC	NC, NC	3.400, 3.400	0.100, 0.100
Min, Max	NC, NC	NC, NC	3.40, 3.40	0.10, 0.10	NC, NC	NC, NC	3.40, 3.40	0.10, 0.10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Leukocytes (10⁹/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	9.867	4.400	4.175	-0.025	7.629	0.126	7.155	0.941
SD	3.3020	2.5159	1.7347	0.9605	3.9764	2.5620	3.7881	2.7556
Median	10.000	5.700	4.100	-0.400	5.850	-0.200	6.000	0.100
Q1, Q3	6.500, 13.100	1.500, 6.000	2.700, 5.650	-0.550, 0.500	5.050, 9.885	-1.835, 0.640	4.800, 10.000	-0.700, 1.500
Min, Max	6.50, 13.10	1.50, 6.00	2.50, 6.00	-0.70, 1.40	4.10, 15.36	-2.00, 5.80	2.50, 15.36	-2.00, 6.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Neutrophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	3.318		4.556		5.858		4.940	
SD	1.4804		2.9225		2.8974		2.7692	
Median	2.810		4.420		4.925		4.030	
Q1, Q3	2.260, 4.375		1.590, 7.150		3.530, 8.190		2.530, 7.110	
Min, Max	2.25, 5.40		1.10, 8.11		2.53, 11.07		1.10, 11.07	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	4.163	0.857	4.077	0.113	5.563	-0.295	4.873	0.016
SD	2.9024	1.3339	3.2847	0.8158	3.0854	1.8723	3.0418	1.5199
Median	3.560	1.290	2.785	-0.055	5.595	-0.220	4.450	-0.030
Q1, Q3	1.610, 7.320	-0.640, 1.920	1.510, 7.680	-0.420, 0.570	4.320, 7.770	-1.520, 1.600	1.980, 7.680	-0.840, 1.480
Min, Max	1.61, 7.32	-0.64, 1.92	1.07, 8.63	-0.84, 1.48	0.00, 9.68	-3.53, 1.95	0.00, 9.68	-3.53, 1.95

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Neutrophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	3.933	0.627	2.078	-0.303	4.651	-0.773	3.762	-0.339
SD	2.6383	1.0510	1.0175	0.4556	3.3401	1.2633	2.7865	1.1276
Median	3.270	1.000	1.750	-0.250	2.850	-0.700	2.840	-0.380
Q1, Q3	1.690, 6.840	-0.560, 1.440	1.380, 2.775	-0.640, 0.035	2.830, 6.270	-1.180, 0.500	2.020, 4.050	-0.890, 0.500
Min, Max	1.69, 6.84	-0.56, 1.44	1.28, 3.53	-0.89, 0.18	2.16, 11.57	-3.19, 0.54	1.28, 11.57	-3.19, 1.44
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	3.005	0.745	2.630	0.250	4.160	-1.996	3.558	-0.963
SD	1.2092	1.1950	2.7519	1.3913	2.0396	1.6772	2.1529	1.9052
Median	3.005	0.745	1.450	-0.285	3.085	-1.110	2.840	-0.660
Q1, Q3	2.150, 3.860	-0.100, 1.590	1.060, 4.200	-0.550, 1.050	2.830, 6.170	-3.910, -0.800	1.950, 5.400	-1.190, -0.200
Min, Max	2.15, 3.86	-0.10, 1.59	0.89, 6.73	-0.74, 2.31	1.95, 7.16	-4.13, -0.20	0.89, 7.16	-4.13, 2.31

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Neutrophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	4.560	2.290	2.148	-0.233	5.550	-0.872	4.223	-0.352
SD	NC	NC	1.3220	0.3119	2.2489	1.2134	2.4175	1.2771
Median	4.560	2.290	1.755	-0.220	4.635	-0.760	4.060	-0.360
Q1, Q3	4.560, 4.560	2.290, 2.290	1.360, 2.935	-0.480, 0.015	3.630, 8.350	-1.780, 0.100	1.810, 4.820	-1.110, 0.110
Min, Max	4.56, 4.56	2.29, 2.29	1.02, 4.06	-0.60, 0.11	3.62, 8.43	-2.64, 0.61	1.02, 8.43	-2.64, 2.29
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	3.520	1.250	2.098	-0.283	18.986	13.494	10.684	6.759
SD	NC	NC	1.0966	0.4232	33.2725	31.0728	23.8577	21.9041
Median	3.520	1.250	1.670	-0.330	4.350	0.510	3.610	0.045
Q1, Q3	3.520, 3.520	1.250, 1.250	1.390, 2.805	-0.610, 0.045	4.310, 4.450	-0.710, 0.780	1.910, 4.350	-0.710, 0.780
Min, Max	3.52, 3.52	1.25, 1.25	1.35, 3.70	-0.72, 0.25	3.32, 78.50	-2.15, 69.04	1.35, 78.50	-2.15, 69.04

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Neutrophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	2.463	0.083	6.010	0.518	4.433	0.324
SD	NC	NC	1.2881	0.3398	4.8694	2.7932	3.9967	1.9992
Median	NC	NC	2.300	0.100	4.480	-0.430	3.290	0.080
Q1, Q3	NC, NC	NC, NC	1.445, 3.480	-0.135, 0.300	3.290, 4.540	-0.740, 0.700	2.890, 4.480	-0.430, 0.480
Min, Max	NC, NC	NC, NC	1.18, 4.07	-0.35, 0.48	3.10, 14.64	-2.12, 5.18	1.18, 14.64	-2.12, 5.18
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	2.033	-0.337	5.143	0.487	3.588	0.075
SD	NC	NC	1.3494	0.4539	1.6097	2.8200	2.1602	1.8619
Median	NC	NC	1.540	-0.100	4.290	0.760	3.850	-0.075
Q1, Q3	NC, NC	NC, NC	1.000, 3.560	-0.860, -0.050	4.140, 7.000	-2.460, 3.160	1.540, 4.290	-0.860, 0.760
Min, Max	NC, NC	NC, NC	1.00, 3.56	-0.86, -0.05	4.14, 7.00	-2.46, 3.16	1.00, 7.00	-2.46, 3.16

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Neutrophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	2.423	0.053	3.795	-1.270	2.972	-0.476
SD	NC	NC	1.8616	0.1343	0.3606	1.8102	1.5263	1.1634
Median	NC	NC	1.740	0.110	3.795	-1.270	3.540	0.010
Q1, Q3	NC, NC	NC, NC	1.000, 4.530	-0.100, 0.150	3.540, 4.050	-2.550, 0.010	1.740, 4.050	-0.100, 0.110
Min, Max	NC, NC	NC, NC	1.00, 4.53	-0.10, 0.15	3.54, 4.05	-2.55, 0.01	1.00, 4.53	-2.55, 0.15
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	1.610	0.020	4.450	-0.615	3.503	-0.403
SD	NC	NC	NC	NC	0.6930	1.4779	1.7113	1.1074
Median	NC	NC	1.610	0.020	4.450	-0.615	3.960	0.020
Q1, Q3	NC, NC	NC, NC	1.610, 1.610	0.020, 0.020	3.960, 4.940	-1.660, 0.430	1.610, 4.940	-1.660, 0.430
Min, Max	NC, NC	NC, NC	1.61, 1.61	0.02, 0.02	3.96, 4.94	-1.66, 0.43	1.61, 4.94	-1.66, 0.43

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Neutrophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	1.580	-0.010	0.500	-3.030	1.040	-1.520
SD	NC	NC	NC	NC	NC	NC	0.7637	2.1355
Median	NC	NC	1.580	-0.010	0.500	-3.030	1.040	-1.520
Q1, Q3	NC, NC	NC, NC	1.580, 1.580	-0.010, -0.010	0.500, 0.500	-3.030, -3.030	0.500, 1.580	-3.030, -0.010
Min, Max	NC, NC	NC, NC	1.58, 1.58	-0.01, -0.01	0.50, 0.50	-3.03, -3.03	0.50, 1.58	-3.03, -0.01
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	1.690	0.100	3.380	-0.150	2.535	-0.025
SD	NC	NC	NC	NC	NC	NC	1.1950	0.1768
Median	NC	NC	1.690	0.100	3.380	-0.150	2.535	-0.025
Q1, Q3	NC, NC	NC, NC	1.690, 1.690	0.100, 0.100	3.380, 3.380	-0.150, -0.150	1.690, 3.380	-0.150, 0.100
Min, Max	NC, NC	NC, NC	1.69, 1.69	0.10, 0.10	3.38, 3.38	-0.15, -0.15	1.69, 3.38	-0.15, 0.10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Neutrophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	5.110	3.520	3.260	-0.270	4.185	1.625
SD	NC	NC	NC	NC	NC	NC	1.3081	2.6799
Median	NC	NC	5.110	3.520	3.260	-0.270	4.185	1.625
Q1, Q3	NC, NC	NC, NC	5.110, 5.110	3.520, 3.520	3.260, 3.260	-0.270, -0.270	3.260, 5.110	-0.270, 3.520
Min, Max	NC, NC	NC, NC	5.11, 5.11	3.52, 3.52	3.26, 3.26	-0.27, -0.27	3.26, 5.11	-0.27, 3.52
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	1.870	0.280	NC	NC	1.870	0.280
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	1.870	0.280	NC	NC	1.870	0.280
Q1, Q3	NC, NC	NC, NC	1.870, 1.870	0.280, 0.280	NC, NC	NC, NC	1.870, 1.870	0.280, 0.280
Min, Max	NC, NC	NC, NC	1.87, 1.87	0.28, 0.28	NC, NC	NC, NC	1.87, 1.87	0.28, 0.28

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Neutrophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	2.090	0.500	NC	NC	2.090	0.500
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	2.090	0.500	NC	NC	2.090	0.500
Q1, Q3	NC, NC	NC, NC	2.090, 2.090	0.500, 0.500	NC, NC	NC, NC	2.090, 2.090	0.500, 0.500
Min, Max	NC, NC	NC, NC	2.09, 2.09	0.50, 0.50	NC, NC	NC, NC	2.09, 2.09	0.50, 0.50
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	1.780	0.190	NC	NC	1.780	0.190
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	1.780	0.190	NC	NC	1.780	0.190
Q1, Q3	NC, NC	NC, NC	1.780, 1.780	0.190, 0.190	NC, NC	NC, NC	1.780, 1.780	0.190, 0.190
Min, Max	NC, NC	NC, NC	1.78, 1.78	0.19, 0.19	NC, NC	NC, NC	1.78, 1.78	0.19, 0.19

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Neutrophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	7.720	4.413	2.655	0.275	5.778	0.566	5.333	1.258
SD	3.9982	2.7408	1.6753	1.0172	3.5209	2.3510	3.5308	2.5964
Median	8.160	5.910	2.650	-0.110	4.110	-0.115	4.050	0.150
Q1, Q3	3.520, 11.480	1.250, 6.080	1.205, 4.105	-0.400, 0.950	3.395, 7.560	-1.020, 2.050	3.260, 8.160	-0.430, 3.630
Min, Max	3.52, 11.48	1.25, 6.08	1.16, 4.16	-0.43, 1.75	3.00, 13.09	-1.93, 4.63	1.16, 13.09	-1.93, 6.08

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lymphocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	1.615		1.016		1.268		1.250	
SD	0.4652		0.3578		0.5454		0.5007	
Median	1.520		0.860		1.045		1.190	
Q1, Q3	1.260, 1.970		0.820, 1.390		0.910, 1.710		0.890, 1.400	
Min, Max	1.19, 2.23		0.47, 1.40		0.60, 2.16		0.47, 2.23	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	1.733	0.150	0.753	-0.295	0.887	-0.381	0.978	-0.270
SD	1.4821	0.9355	0.4239	0.2752	0.2456	0.3447	0.6638	0.4627
Median	0.990	-0.200	0.600	-0.255	0.860	-0.275	0.840	-0.250
Q1, Q3	0.770, 3.440	-0.560, 1.210	0.540, 1.040	-0.350, -0.190	0.680, 1.040	-0.670, -0.110	0.590, 1.040	-0.560, -0.110
Min, Max	0.77, 3.44	-0.56, 1.21	0.28, 1.46	-0.78, 0.06	0.57, 1.32	-1.01, -0.01	0.28, 3.44	-1.01, 1.21

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lymphocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	1.160	-0.423	0.785	-0.458	0.727	-0.680	0.836	-0.561
SD	0.7674	0.2031	0.1047	0.1630	0.1863	0.5067	0.3749	0.3825
Median	0.810	-0.520	0.805	-0.510	0.730	-0.470	0.795	-0.510
Q1, Q3	0.630, 2.040	-0.560, -0.190	0.720, 0.850	-0.555, -0.360	0.610, 0.870	-1.150, -0.360	0.640, 0.870	-0.590, -0.360
Min, Max	0.63, 2.04	-0.56, -0.19	0.64, 0.89	-0.59, -0.22	0.44, 1.01	-1.35, 0.01	0.44, 2.04	-1.35, 0.01
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	1.550	-0.160	0.715	-0.528	0.890	-0.430	0.934	-0.419
SD	1.1455	0.4101	0.2461	0.3908	0.3625	0.5982	0.5099	0.5049
Median	1.550	-0.160	0.755	-0.505	0.960	-0.635	0.865	-0.460
Q1, Q3	0.740, 2.360	-0.450, 0.130	0.555, 0.875	-0.805, -0.250	0.640, 1.125	-0.890, 0.135	0.730, 1.070	-0.820, -0.080
Min, Max	0.74, 2.36	-0.45, 0.13	0.38, 0.97	-1.02, -0.08	0.30, 1.37	-1.09, 0.43	0.30, 2.36	-1.09, 0.43

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lymphocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	2.220	-0.010	0.830	-0.413	0.927	-0.517	1.009	-0.433
SD	NC	NC	0.1349	0.2830	0.2648	0.5005	0.4517	0.4142
Median	2.220	-0.010	0.835	-0.485	0.845	-0.570	0.840	-0.410
Q1, Q3	2.220, 2.220	-0.010, -0.010	0.745, 0.915	-0.615, -0.210	0.770, 0.980	-0.850, -0.180	0.770, 0.990	-0.730, -0.020
Min, Max	2.22, 2.22	-0.01, -0.01	0.66, 0.99	-0.66, -0.02	0.69, 1.43	-1.16, 0.23	0.66, 2.22	-1.16, 0.23
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	2.410	0.180	0.835	-0.408	0.916	-0.696	1.033	-0.493
SD	NC	NC	0.1318	0.2579	0.2001	0.3988	0.5092	0.4115
Median	2.410	0.180	0.780	-0.465	0.980	-0.630	0.890	-0.465
Q1, Q3	2.410, 2.410	0.180, 0.180	0.755, 0.915	-0.600, -0.215	0.740, 1.080	-1.030, -0.360	0.750, 1.080	-0.640, -0.280
Min, Max	2.41, 2.41	0.18, 0.18	0.75, 1.03	-0.64, -0.06	0.67, 1.11	-1.18, -0.28	0.67, 2.41	-1.18, 0.18

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lymphocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	0.765	-0.478	0.882	-0.730	0.830	-0.618
SD	NC	NC	0.3454	0.2951	0.1558	0.5307	0.2463	0.4372
Median	NC	NC	0.800	-0.335	0.870	-0.760	0.870	-0.360
Q1, Q3	NC, NC	NC, NC	0.470, 1.060	-0.630, -0.325	0.740, 0.950	-1.030, -0.360	0.740, 1.060	-0.920, -0.330
Min, Max	NC, NC	NC, NC	0.40, 1.06	-0.92, -0.32	0.74, 1.11	-1.42, -0.08	0.40, 1.11	-1.42, -0.08
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	0.970	-0.400	0.700	-0.553	0.835	-0.477
SD	NC	NC	0.1200	0.1229	0.3292	0.0929	0.2664	0.1286
Median	NC	NC	0.970	-0.350	0.520	-0.580	0.910	-0.495
Q1, Q3	NC, NC	NC, NC	0.850, 1.090	-0.540, -0.310	0.500, 1.080	-0.630, -0.450	0.520, 1.080	-0.580, -0.350
Min, Max	NC, NC	NC, NC	0.85, 1.09	-0.54, -0.31	0.50, 1.08	-0.63, -0.45	0.50, 1.09	-0.63, -0.31

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lymphocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	1.000	-0.370	0.620	-0.405	0.848	-0.384
SD	NC	NC	0.1758	0.1473	0.3253	0.2192	0.2919	0.1524
Median	NC	NC	0.930	-0.450	0.620	-0.405	0.870	-0.450
Q1, Q3	NC, NC	NC, NC	0.870, 1.200	-0.460, -0.200	0.390, 0.850	-0.560, -0.250	0.850, 0.930	-0.460, -0.250
Min, Max	NC, NC	NC, NC	0.87, 1.20	-0.46, -0.20	0.39, 0.85	-0.56, -0.25	0.39, 1.20	-0.56, -0.20
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	1.040	-0.280	0.600	-0.425	0.747	-0.377
SD	NC	NC	NC	NC	0.2546	0.1485	0.3113	0.1343
Median	NC	NC	1.040	-0.280	0.600	-0.425	0.780	-0.320
Q1, Q3	NC, NC	NC, NC	1.040, 1.040	-0.280, -0.280	0.420, 0.780	-0.530, -0.320	0.420, 1.040	-0.530, -0.280
Min, Max	NC, NC	NC, NC	1.04, 1.04	-0.28, -0.28	0.42, 0.78	-0.53, -0.32	0.42, 1.04	-0.53, -0.28

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lymphocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.960	-0.360	0.670	-0.430	0.815	-0.395
SD	NC	NC	NC	NC	NC	NC	0.2051	0.0495
Median	NC	NC	0.960	-0.360	0.670	-0.430	0.815	-0.395
Q1, Q3	NC, NC	NC, NC	0.960, 0.960	-0.360, -0.360	0.670, 0.670	-0.430, -0.430	0.670, 0.960	-0.430, -0.360
Min, Max	NC, NC	NC, NC	0.96, 0.96	-0.36, -0.36	0.67, 0.67	-0.43, -0.43	0.67, 0.96	-0.43, -0.36
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	1.190	-0.130	0.730	-0.370	0.960	-0.250
SD	NC	NC	NC	NC	NC	NC	0.3253	0.1697
Median	NC	NC	1.190	-0.130	0.730	-0.370	0.960	-0.250
Q1, Q3	NC, NC	NC, NC	1.190, 1.190	-0.130, -0.130	0.730, 0.730	-0.370, -0.370	0.730, 1.190	-0.370, -0.130
Min, Max	NC, NC	NC, NC	1.19, 1.19	-0.13, -0.13	0.73, 0.73	-0.37, -0.37	0.73, 1.19	-0.37, -0.13

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lymphocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	1.840	0.520	0.860	-0.240	1.350	0.140
SD	NC	NC	NC	NC	NC	NC	0.6930	0.5374
Median	NC	NC	1.840	0.520	0.860	-0.240	1.350	0.140
Q1, Q3	NC, NC	NC, NC	1.840, 1.840	0.520, 0.520	0.860, 0.860	-0.240, -0.240	0.860, 1.840	-0.240, 0.520
Min, Max	NC, NC	NC, NC	1.84, 1.84	0.52, 0.52	0.86, 0.86	-0.24, -0.24	0.86, 1.84	-0.24, 0.52
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	1.320	0.000	NC	NC	1.320	0.000
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	1.320	0.000	NC	NC	1.320	0.000
Q1, Q3	NC, NC	NC, NC	1.320, 1.320	0.000, 0.000	NC, NC	NC, NC	1.320, 1.320	0.000, 0.000
Min, Max	NC, NC	NC, NC	1.32, 1.32	0.00, 0.00	NC, NC	NC, NC	1.32, 1.32	0.00, 0.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lymphocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	1.420	0.100	NC	NC	1.420	0.100
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	1.420	0.100	NC	NC	1.420	0.100
Q1, Q3	NC, NC	NC, NC	1.420, 1.420	0.100, 0.100	NC, NC	NC, NC	1.420, 1.420	0.100, 0.100
Min, Max	NC, NC	NC, NC	1.42, 1.42	0.10, 0.10	NC, NC	NC, NC	1.42, 1.42	0.10, 0.10
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	1.210	-0.110	NC	NC	1.210	-0.110
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	1.210	-0.110	NC	NC	1.210	-0.110
Q1, Q3	NC, NC	NC, NC	1.210, 1.210	-0.110, -0.110	NC, NC	NC, NC	1.210, 1.210	-0.110, -0.110
Min, Max	NC, NC	NC, NC	1.21, 1.21	-0.11, -0.11	NC, NC	NC, NC	1.21, 1.21	-0.11, -0.11

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lymphocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	1.270	-0.313	0.968	-0.275	1.015	-0.384	1.053	-0.341
SD	0.9875	0.4366	0.3464	0.2583	0.6095	0.6863	0.6031	0.5286
Median	0.720	-0.470	0.990	-0.225	0.850	-0.230	0.840	-0.240
Q1, Q3	0.680, 2.410	-0.650, 0.180	0.675, 1.260	-0.450, -0.100	0.665, 1.100	-0.770, -0.110	0.680, 1.220	-0.630, -0.070
Min, Max	0.68, 2.41	-0.65, 0.18	0.59, 1.30	-0.63, -0.02	0.47, 2.42	-1.56, 0.71	0.47, 2.42	-1.56, 0.71

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Monocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	0.453		0.606		0.615		0.581	
SD	0.0591		0.3401		0.2526		0.2609	
Median	0.460		0.580		0.530		0.500	
Q1, Q3	0.405, 0.500		0.410, 0.720		0.410, 0.730		0.410, 0.610	
Min, Max	0.38, 0.51		0.21, 1.28		0.39, 1.11		0.21, 1.28	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	0.417	-0.017	0.503	-0.102	0.629	0.014	0.556	-0.027
SD	0.0757	0.0351	0.3128	0.0703	0.3126	0.2194	0.2895	0.1685
Median	0.450	-0.020	0.445	-0.090	0.545	-0.020	0.470	-0.040
Q1, Q3	0.330, 0.470	-0.050, 0.020	0.320, 0.580	-0.140, -0.040	0.390, 0.910	-0.070, 0.080	0.340, 0.620	-0.090, 0.020
Min, Max	0.33, 0.47	-0.05, 0.02	0.17, 1.06	-0.22, -0.03	0.28, 1.26	-0.28, 0.53	0.17, 1.26	-0.28, 0.53

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Monocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	0.443	0.010	0.368	-0.075	0.597	-0.013	0.499	-0.026
SD	0.1861	0.1311	0.1763	0.0545	0.3906	0.1510	0.3068	0.1224
Median	0.420	-0.010	0.380	-0.065	0.420	-0.050	0.415	-0.050
Q1, Q3	0.270, 0.640	-0.110, 0.150	0.255, 0.480	-0.110, -0.040	0.360, 0.800	-0.080, 0.000	0.360, 0.570	-0.080, -0.010
Min, Max	0.27, 0.64	-0.11, 0.15	0.14, 0.57	-0.15, -0.02	0.34, 1.41	-0.19, 0.30	0.14, 1.41	-0.19, 0.30
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	0.445	0.040	0.338	-0.105	0.446	-0.174	0.415	-0.124
SD	0.0919	0.0566	0.1721	0.0695	0.1504	0.1459	0.1492	0.1364
Median	0.445	0.040	0.310	-0.105	0.410	-0.140	0.385	-0.090
Q1, Q3	0.380, 0.510	0.000, 0.080	0.205, 0.470	-0.165, -0.045	0.340, 0.555	-0.285, -0.050	0.330, 0.510	-0.170, -0.040
Min, Max	0.38, 0.51	0.00, 0.08	0.17, 0.56	-0.17, -0.04	0.27, 0.69	-0.42, -0.02	0.17, 0.69	-0.42, 0.08

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Monocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	0.560	0.130	0.430	-0.013	0.615	-0.053	0.543	-0.022
SD	NC	NC	0.2235	0.0624	0.2430	0.1194	0.2297	0.1060
Median	0.560	0.130	0.415	-0.020	0.590	-0.025	0.480	-0.020
Q1, Q3	0.560, 0.560	0.130, 0.130	0.265, 0.595	-0.055, 0.030	0.390, 0.740	-0.110, -0.020	0.380, 0.710	-0.080, 0.070
Min, Max	0.56, 0.56	0.13, 0.13	0.18, 0.71	-0.08, 0.07	0.38, 1.00	-0.25, 0.11	0.18, 1.00	-0.25, 0.13
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	0.440	0.010	0.420	-0.023	0.612	0.008	0.518	-0.004
SD	NC	NC	0.2685	0.0842	0.2888	0.1318	0.2664	0.1017
Median	0.440	0.010	0.400	-0.025	0.530	-0.010	0.470	0.000
Q1, Q3	0.440, 0.440	0.010, 0.010	0.225, 0.615	-0.095, 0.050	0.470, 0.610	-0.060, 0.060	0.350, 0.610	-0.090, 0.060
Min, Max	0.44, 0.44	0.01, 0.01	0.12, 0.76	-0.10, 0.06	0.35, 1.10	-0.15, 0.20	0.12, 1.10	-0.15, 0.20

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Monocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	0.413	-0.030	0.556	-0.048	0.492	-0.040
SD	NC	NC	0.1945	0.0516	0.2670	0.1452	0.2357	0.1078
Median	NC	NC	0.430	-0.030	0.490	-0.100	0.460	-0.050
Q1, Q3	NC, NC	NC, NC	0.280, 0.545	-0.070, 0.010	0.360, 0.610	-0.120, -0.050	0.360, 0.610	-0.100, -0.010
Min, Max	NC, NC	NC, NC	0.16, 0.63	-0.09, 0.03	0.33, 0.99	-0.17, 0.20	0.16, 0.99	-0.17, 0.20
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	0.377	-0.070	0.513	0.043	0.445	-0.013
SD	NC	NC	0.2411	0.0173	0.0907	0.0839	0.1793	0.0824
Median	NC	NC	0.350	-0.060	0.550	0.000	0.480	-0.035
Q1, Q3	NC, NC	NC, NC	0.150, 0.630	-0.090, -0.060	0.410, 0.580	-0.010, 0.140	0.350, 0.580	-0.060, 0.000
Min, Max	NC, NC	NC, NC	0.15, 0.63	-0.09, -0.06	0.41, 0.58	-0.01, 0.14	0.15, 0.63	-0.09, 0.14

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Monocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	0.457	0.010	0.470	-0.030	0.462	-0.006
SD	NC	NC	0.2501	0.0265	0.1273	0.0000	0.1881	0.0288
Median	NC	NC	0.450	0.000	0.470	-0.030	0.450	-0.010
Q1, Q3	NC, NC	NC, NC	0.210, 0.710	-0.010, 0.040	0.380, 0.560	-0.030, -0.030	0.380, 0.560	-0.030, 0.000
Min, Max	NC, NC	NC, NC	0.21, 0.71	-0.01, 0.04	0.38, 0.56	-0.03, -0.03	0.21, 0.71	-0.03, 0.04
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	0.370	-0.040	0.485	-0.015	0.447	-0.023
SD	NC	NC	NC	NC	0.2051	0.0778	0.1595	0.0569
Median	NC	NC	0.370	-0.040	0.485	-0.015	0.370	-0.040
Q1, Q3	NC, NC	NC, NC	0.370, 0.370	-0.040, -0.040	0.340, 0.630	-0.070, 0.040	0.340, 0.630	-0.070, 0.040
Min, Max	NC, NC	NC, NC	0.37, 0.37	-0.04, -0.04	0.34, 0.63	-0.07, 0.04	0.34, 0.63	-0.07, 0.04

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Monocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.370	-0.040	0.390	-0.020	0.380	-0.030
SD	NC	NC	NC	NC	NC	NC	0.0141	0.0141
Median	NC	NC	0.370	-0.040	0.390	-0.020	0.380	-0.030
Q1, Q3	NC, NC	NC, NC	0.370, 0.370	-0.040, -0.040	0.390, 0.390	-0.020, -0.020	0.370, 0.390	-0.040, -0.020
Min, Max	NC, NC	NC, NC	0.37, 0.37	-0.04, -0.04	0.39, 0.39	-0.02, -0.02	0.37, 0.39	-0.04, -0.02
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.440	0.030	0.340	-0.070	0.390	-0.020
SD	NC	NC	NC	NC	NC	NC	0.0707	0.0707
Median	NC	NC	0.440	0.030	0.340	-0.070	0.390	-0.020
Q1, Q3	NC, NC	NC, NC	0.440, 0.440	0.030, 0.030	0.340, 0.340	-0.070, -0.070	0.340, 0.440	-0.070, 0.030
Min, Max	NC, NC	NC, NC	0.44, 0.44	0.03, 0.03	0.34, 0.34	-0.07, -0.07	0.34, 0.44	-0.07, 0.03

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Monocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.920	0.510	0.400	-0.010	0.660	0.250
SD	NC	NC	NC	NC	NC	NC	0.3677	0.3677
Median	NC	NC	0.920	0.510	0.400	-0.010	0.660	0.250
Q1, Q3	NC, NC	NC, NC	0.920, 0.920	0.510, 0.510	0.400, 0.400	-0.010, -0.010	0.400, 0.920	-0.010, 0.510
Min, Max	NC, NC	NC, NC	0.92, 0.92	0.51, 0.51	0.40, 0.40	-0.01, -0.01	0.40, 0.92	-0.01, 0.51
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.450	0.040	NC	NC	0.450	0.040
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.450	0.040	NC	NC	0.450	0.040
Q1, Q3	NC, NC	NC, NC	0.450, 0.450	0.040, 0.040	NC, NC	NC, NC	0.450, 0.450	0.040, 0.040
Min, Max	NC, NC	NC, NC	0.45, 0.45	0.04, 0.04	NC, NC	NC, NC	0.45, 0.45	0.04, 0.04

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Monocytes (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.610	0.200	NC	NC	0.610	0.200
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.610	0.200	NC	NC	0.610	0.200
Q1, Q3	NC, NC	NC, NC	0.610, 0.610	0.200, 0.200	NC, NC	NC, NC	0.610, 0.610	0.200, 0.200
Min, Max	NC, NC	NC, NC	0.61, 0.61	0.20, 0.20	NC, NC	NC, NC	0.61, 0.61	0.20, 0.20
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.450	0.040	NC	NC	0.450	0.040
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.450	0.040	NC	NC	0.450	0.040
Q1, Q3	NC, NC	NC, NC	0.450, 0.450	0.040, 0.040	NC, NC	NC, NC	0.450, 0.450	0.040, 0.040
Min, Max	NC, NC	NC, NC	0.45, 0.45	0.04, 0.04	NC, NC	NC, NC	0.45, 0.45	0.04, 0.04

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Monocytes (10⁹/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	0.697	0.263	0.448	0.005	0.535	-0.019	0.544	0.044
SD	0.2346	0.2550	0.1520	0.0686	0.2431	0.2157	0.2238	0.2158
Median	0.750	0.260	0.450	0.025	0.445	-0.035	0.450	0.000
Q1, Q3	0.440, 0.900	0.010, 0.520	0.345, 0.550	-0.045, 0.055	0.400, 0.690	-0.125, 0.020	0.400, 0.750	-0.090, 0.060
Min, Max	0.44, 0.90	0.01, 0.52	0.26, 0.63	-0.09, 0.06	0.25, 0.96	-0.31, 0.44	0.25, 0.96	-0.31, 0.52

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Eosinophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value			Value		Value		Value	
Baseline								
Nx	4		7		10		21	
Mean	0.103		0.087		0.486		0.280	
SD	0.0419		0.0565		0.7757		0.5591	
Median	0.120		0.090		0.145		0.120	
Q1, Q3	0.080, 0.125		0.030, 0.140		0.100, 0.290		0.090, 0.160	
Min, Max	0.04, 0.13		0.00, 0.16		0.04, 2.40		0.00, 2.40	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	0.113	0.017	0.068	-0.018	0.272	-0.214	0.183	-0.116
SD	0.0252	0.0503	0.0475	0.0172	0.3520	0.6852	0.2688	0.4966
Median	0.110	0.010	0.085	-0.010	0.160	-0.005	0.110	-0.010
Q1, Q3	0.090, 0.140	-0.030, 0.070	0.020, 0.100	-0.040, -0.010	0.110, 0.250	-0.090, 0.010	0.090, 0.170	-0.040, 0.010
Min, Max	0.09, 0.14	-0.03, 0.07	0.00, 0.12	-0.04, 0.00	0.04, 1.24	-2.15, 0.20	0.00, 1.24	-2.15, 0.20

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Eosinophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	0.157	0.060	0.080	-0.018	0.264	-0.390	0.189	-0.187
SD	0.0208	0.0693	0.0589	0.0287	0.2149	0.8331	0.1706	0.6053
Median	0.150	0.020	0.090	-0.005	0.210	-0.020	0.140	0.000
Q1, Q3	0.140, 0.180	0.020, 0.140	0.040, 0.120	-0.035, 0.000	0.110, 0.380	-0.650, 0.030	0.100, 0.210	-0.020, 0.030
Min, Max	0.14, 0.18	0.02, 0.14	0.00, 0.14	-0.06, 0.00	0.10, 0.70	-2.19, 0.09	0.00, 0.70	-2.19, 0.14
Cycle 2 Day 1								
Nx	2	2	3	3	8	8	13	13
Mean	0.195	0.110	0.120	-0.010	0.211	-0.374	0.188	-0.215
SD	0.1202	0.0566	0.0458	0.0200	0.2313	0.8629	0.1852	0.6926
Median	0.195	0.110	0.110	-0.010	0.110	-0.025	0.110	-0.010
Q1, Q3	0.110, 0.280	0.070, 0.150	0.080, 0.170	-0.030, 0.010	0.075, 0.335	-0.495, 0.020	0.090, 0.170	-0.030, 0.050
Min, Max	0.11, 0.28	0.07, 0.15	0.08, 0.17	-0.03, 0.01	0.01, 0.64	-2.34, 0.35	0.01, 0.64	-2.34, 0.35

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Eosinophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	0.090	0.050	0.093	-0.005	0.272	-0.482	0.190	-0.260
SD	NC	NC	0.0680	0.0100	0.2133	0.9101	0.1815	0.6923
Median	0.090	0.050	0.105	0.000	0.230	-0.045	0.160	0.000
Q1, Q3	0.090, 0.090	0.050, 0.050	0.045, 0.140	-0.010, 0.000	0.170, 0.370	-0.720, 0.070	0.090, 0.260	-0.160, 0.070
Min, Max	0.09, 0.09	0.05, 0.05	0.00, 0.16	-0.02, 0.00	0.00, 0.63	-2.23, 0.08	0.00, 0.63	-2.23, 0.08
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	0.060	0.020	0.103	0.005	0.386	-0.038	0.240	-0.015
SD	NC	NC	0.0842	0.0387	0.4421	0.1043	0.3363	0.0771
Median	0.060	0.020	0.105	-0.005	0.190	-0.010	0.150	-0.005
Q1, Q3	0.060, 0.060	0.020, 0.020	0.040, 0.165	-0.020, 0.030	0.170, 0.280	-0.100, 0.010	0.080, 0.200	-0.030, 0.020
Min, Max	0.06, 0.06	0.02, 0.02	0.00, 0.20	-0.03, 0.06	0.12, 1.17	-0.18, 0.09	0.00, 1.17	-0.18, 0.09

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Eosinophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	0.088	-0.010	0.384	-0.040	0.252	-0.027
SD	NC	NC	0.0608	0.0183	0.3923	0.1453	0.3205	0.1045
Median	NC	NC	0.105	-0.010	0.220	0.010	0.140	0.000
Q1, Q3	NC, NC	NC, NC	0.050, 0.125	-0.025, 0.005	0.200, 0.280	-0.070, 0.010	0.110, 0.220	-0.030, 0.010
Min, Max	NC, NC	NC, NC	0.00, 0.14	-0.03, 0.01	0.14, 1.08	-0.27, 0.12	0.00, 1.08	-0.27, 0.12
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	0.067	-0.010	0.110	-0.050	0.088	-0.030
SD	NC	NC	0.0611	0.0100	0.0954	0.0819	0.0755	0.0566
Median	NC	NC	0.080	-0.010	0.100	-0.030	0.090	-0.015
Q1, Q3	NC, NC	NC, NC	0.000, 0.120	-0.020, 0.000	0.020, 0.210	-0.140, 0.020	0.020, 0.120	-0.030, 0.000
Min, Max	NC, NC	NC, NC	0.00, 0.12	-0.02, 0.00	0.02, 0.21	-0.14, 0.02	0.00, 0.21	-0.14, 0.02

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Eosinophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	0.080	0.003	0.165	-0.010	0.114	-0.002
SD	NC	NC	0.0854	0.0252	0.0919	0.0707	0.0891	0.0402
Median	NC	NC	0.070	0.000	0.165	-0.010	0.100	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.170	-0.020, 0.030	0.100, 0.230	-0.060, 0.040	0.070, 0.170	-0.020, 0.030
Min, Max	NC, NC	NC, NC	0.00, 0.17	-0.02, 0.03	0.10, 0.23	-0.06, 0.04	0.00, 0.23	-0.06, 0.04
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	0.000	0.000	0.265	0.090	0.177	0.060
SD	NC	NC	NC	NC	0.0778	0.0990	0.1626	0.0872
Median	NC	NC	0.000	0.000	0.265	0.090	0.210	0.020
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	0.210, 0.320	0.020, 0.160	0.000, 0.320	0.000, 0.160
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	0.21, 0.32	0.02, 0.16	0.00, 0.32	0.00, 0.16

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Eosinophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.000	0.000	0.220	0.030	0.110	0.015
SD	NC	NC	NC	NC	NC	NC	0.1556	0.0212
Median	NC	NC	0.000	0.000	0.220	0.030	0.110	0.015
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	0.220, 0.220	0.030, 0.030	0.000, 0.220	0.000, 0.030
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	0.22, 0.22	0.03, 0.03	0.00, 0.22	0.00, 0.03
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.000	0.000	0.220	0.030	0.110	0.015
SD	NC	NC	NC	NC	NC	NC	0.1556	0.0212
Median	NC	NC	0.000	0.000	0.220	0.030	0.110	0.015
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	0.220, 0.220	0.030, 0.030	0.000, 0.220	0.000, 0.030
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	0.22, 0.22	0.03, 0.03	0.00, 0.22	0.00, 0.03

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Eosinophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.000	0.000	0.190	0.000	0.095	0.000
SD	NC	NC	NC	NC	NC	NC	0.1344	0.0000
Median	NC	NC	0.000	0.000	0.190	0.000	0.095	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	0.190, 0.190	0.000, 0.000	0.000, 0.190	0.000, 0.000
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	0.19, 0.19	0.00, 0.00	0.00, 0.19	0.00, 0.00
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.000	0.000	NC	NC	0.000	0.000
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.000	0.000	NC	NC	0.000	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Eosinophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.000	0.000	NC	NC	0.000	0.000
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.000	0.000	NC	NC	0.000	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.000	0.000	NC	NC	0.000	0.000
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.000	0.000	NC	NC	0.000	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Eosinophils (10⁹/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	0.113	0.017	0.090	-0.008	0.226	-0.071	0.167	-0.037
SD	0.0551	0.0351	0.0841	0.0512	0.1761	0.2767	0.1475	0.2014
Median	0.110	0.020	0.080	-0.015	0.185	-0.010	0.110	0.000
Q1, Q3	0.060, 0.170	-0.020, 0.050	0.030, 0.150	-0.045, 0.030	0.095, 0.285	-0.030, 0.055	0.070, 0.200	-0.030, 0.050
Min, Max	0.06, 0.17	-0.02, 0.05	0.00, 0.20	-0.06, 0.06	0.07, 0.61	-0.74, 0.14	0.00, 0.61	-0.74, 0.14

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Basophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4	Change from baseline	N=7	Change from baseline	N=10	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	0.033		0.029		0.121		0.073	
SD	0.0150		0.0212		0.2398		0.1680	
Median	0.030		0.040		0.045		0.040	
Q1, Q3	0.020, 0.045		0.010, 0.050		0.030, 0.060		0.020, 0.050	
Min, Max	0.02, 0.05		0.00, 0.05		0.02, 0.80		0.00, 0.80	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	0.040	0.003	0.018	-0.007	0.047	-0.074	0.037	-0.041
SD	0.0173	0.0058	0.0147	0.0082	0.0275	0.2276	0.0254	0.1650
Median	0.050	0.000	0.015	-0.005	0.040	-0.010	0.030	0.000
Q1, Q3	0.020, 0.050	0.000, 0.010	0.010, 0.030	-0.010, 0.000	0.030, 0.050	-0.020, 0.010	0.020, 0.050	-0.020, 0.010
Min, Max	0.02, 0.05	0.00, 0.01	0.00, 0.04	-0.02, 0.00	0.02, 0.11	-0.72, 0.02	0.00, 0.11	-0.72, 0.02

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Basophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	0.023	-0.013	0.013	-0.005	0.043	-0.114	0.030	-0.061
SD	0.0153	0.0058	0.0096	0.0173	0.0335	0.2762	0.0277	0.1957
Median	0.020	-0.010	0.015	0.000	0.030	-0.010	0.020	-0.010
Q1, Q3	0.010, 0.040	-0.020, -0.010	0.005, 0.020	-0.015, 0.005	0.020, 0.060	-0.030, -0.010	0.010, 0.040	-0.020, 0.000
Min, Max	0.01, 0.04	-0.02, -0.01	0.00, 0.02	-0.03, 0.01	0.01, 0.11	-0.74, 0.01	0.00, 0.11	-0.74, 0.01
Cycle 2 Day 1								
Nx	2	2	3	3	8	8	13	13
Mean	0.035	0.000	0.013	-0.010	0.041	-0.103	0.034	-0.065
SD	0.0212	0.0000	0.0058	0.0173	0.0196	0.2618	0.0202	0.2060
Median	0.035	0.000	0.010	0.000	0.040	-0.010	0.040	0.000
Q1, Q3	0.020, 0.050	0.000, 0.000	0.010, 0.020	-0.030, 0.000	0.030, 0.055	-0.025, 0.000	0.020, 0.050	-0.020, 0.000
Min, Max	0.02, 0.05	0.00, 0.00	0.01, 0.02	-0.03, 0.00	0.01, 0.07	-0.75, 0.00	0.01, 0.07	-0.75, 0.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Basophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	0.040	-0.010	0.015	-0.003	0.048	-0.123	0.035	-0.069
SD	NC	NC	0.0238	0.0050	0.0172	0.3075	0.0242	0.2263
Median	0.040	-0.010	0.005	0.000	0.045	-0.005	0.040	0.000
Q1, Q3	0.040, 0.040	-0.010, -0.010	0.000, 0.030	-0.005, 0.000	0.040, 0.050	-0.020, 0.020	0.010, 0.050	-0.020, 0.010
Min, Max	0.04, 0.04	-0.01, -0.01	0.00, 0.05	-0.01, 0.00	0.03, 0.08	-0.75, 0.02	0.00, 0.08	-0.75, 0.02
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	0.040	-0.010	0.013	-0.005	0.048	0.002	0.033	-0.002
SD	NC	NC	0.0126	0.0100	0.0277	0.0217	0.0267	0.0162
Median	0.040	-0.010	0.010	0.000	0.040	0.010	0.030	0.000
Q1, Q3	0.040, 0.040	-0.010, -0.010	0.005, 0.020	-0.010, 0.000	0.030, 0.060	-0.010, 0.020	0.010, 0.040	-0.010, 0.010
Min, Max	0.04, 0.04	-0.01, -0.01	0.00, 0.03	-0.02, 0.00	0.02, 0.09	-0.03, 0.02	0.00, 0.09	-0.03, 0.02

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Basophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	0.018	-0.000	0.044	-0.002	0.032	-0.001
SD	NC	NC	0.0171	0.0082	0.0305	0.0192	0.0277	0.0145
Median	NC	NC	0.015	0.000	0.030	0.000	0.020	0.000
Q1, Q3	NC, NC	NC, NC	0.005, 0.030	-0.005, 0.005	0.020, 0.060	-0.010, 0.010	0.020, 0.040	-0.010, 0.010
Min, Max	NC, NC	NC, NC	0.00, 0.04	-0.01, 0.01	0.02, 0.09	-0.03, 0.02	0.00, 0.09	-0.03, 0.02
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	0.020	0.000	0.037	0.010	0.028	0.005
SD	NC	NC	0.0265	0.0000	0.0153	0.0100	0.0214	0.0084
Median	NC	NC	0.010	0.000	0.040	0.010	0.030	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.050	0.000, 0.000	0.020, 0.050	0.000, 0.020	0.010, 0.050	0.000, 0.010
Min, Max	NC, NC	NC, NC	0.00, 0.05	0.00, 0.00	0.02, 0.05	0.00, 0.02	0.00, 0.05	0.00, 0.02

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Basophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	0.020	-0.000	0.035	0.005	0.026	0.002
SD	NC	NC	0.0200	0.0100	0.0212	0.0071	0.0195	0.0084
Median	NC	NC	0.020	0.000	0.035	0.005	0.020	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.040	-0.010, 0.010	0.020, 0.050	0.000, 0.010	0.020, 0.040	0.000, 0.010
Min, Max	NC, NC	NC, NC	0.00, 0.04	-0.01, 0.01	0.02, 0.05	0.00, 0.01	0.00, 0.05	-0.01, 0.01
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	0.010	0.010	0.040	0.010	0.030	0.010
SD	NC	NC	NC	NC	0.0000	0.0141	0.0173	0.0100
Median	NC	NC	0.010	0.010	0.040	0.010	0.040	0.010
Q1, Q3	NC, NC	NC, NC	0.010, 0.010	0.010, 0.010	0.040, 0.040	0.000, 0.020	0.010, 0.040	0.000, 0.020
Min, Max	NC, NC	NC, NC	0.01, 0.01	0.01, 0.01	0.04, 0.04	0.00, 0.02	0.01, 0.04	0.00, 0.02

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Basophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.000	0.000	0.050	0.010	0.025	0.005
SD	NC	NC	NC	NC	NC	NC	0.0354	0.0071
Median	NC	NC	0.000	0.000	0.050	0.010	0.025	0.005
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	0.050, 0.050	0.010, 0.010	0.000, 0.050	0.000, 0.010
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	0.05, 0.05	0.01, 0.01	0.00, 0.05	0.00, 0.01
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.000	0.000	0.040	0.000	0.020	0.000
SD	NC	NC	NC	NC	NC	NC	0.0283	0.0000
Median	NC	NC	0.000	0.000	0.040	0.000	0.020	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	0.040, 0.040	0.000, 0.000	0.000, 0.040	0.000, 0.000
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	0.04, 0.04	0.00, 0.00	0.00, 0.04	0.00, 0.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Basophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.100	0.100	0.050	0.010	0.075	0.055
SD	NC	NC	NC	NC	NC	NC	0.0354	0.0636
Median	NC	NC	0.100	0.100	0.050	0.010	0.075	0.055
Q1, Q3	NC, NC	NC, NC	0.100, 0.100	0.100, 0.100	0.050, 0.050	0.010, 0.010	0.050, 0.100	0.010, 0.100
Min, Max	NC, NC	NC, NC	0.10, 0.10	0.10, 0.10	0.05, 0.05	0.01, 0.01	0.05, 0.10	0.01, 0.10
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	1.000	1.000	NC	NC	1.000	1.000
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	1.000	1.000	NC	NC	1.000	1.000
Q1, Q3	NC, NC	NC, NC	1.000, 1.000	1.000, 1.000	NC, NC	NC, NC	1.000, 1.000	1.000, 1.000
Min, Max	NC, NC	NC, NC	1.00, 1.00	1.00, 1.00	NC, NC	NC, NC	1.00, 1.00	1.00, 1.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Basophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.000	0.000	NC	NC	0.000	0.000
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.000	0.000	NC	NC	0.000	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.000	0.000	NC	NC	0.000	0.000
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.000	0.000	NC	NC	0.000	0.000
Q1, Q3	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000	NC, NC	NC, NC	0.000, 0.000	0.000, 0.000
Min, Max	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00	NC, NC	NC, NC	0.00, 0.00	0.00, 0.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.1
Summary of Hematology Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Basophils (10⁹/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	0.057	0.020	0.018	-0.000	0.054	0.006	0.045	0.007
SD	0.0208	0.0361	0.0171	0.0082	0.0256	0.0239	0.0272	0.0231
Median	0.050	0.010	0.015	0.000	0.050	0.000	0.040	0.000
Q1, Q3	0.040, 0.080	-0.010, 0.060	0.005, 0.030	-0.005, 0.005	0.030, 0.070	-0.005, 0.010	0.030, 0.060	-0.010, 0.010
Min, Max	0.04, 0.08	-0.01, 0.06	0.00, 0.04	-0.01, 0.01	0.03, 0.10	-0.02, 0.06	0.00, 0.10	-0.02, 0.06

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urea Nitrogen (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	6.43		4.91		6.43		5.92	
SD	3.362		0.798		2.475		2.276	
Median	5.71		4.64		6.23		5.36	
Q1, Q3	3.75, 9.10		4.28, 5.71		4.28, 8.21		4.28, 7.20	
Min, Max	3.6, 10.7		3.9, 6.2		2.9, 10.7		2.9, 10.7	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	4.64	-0.36	6.18	1.10	7.47	1.04	6.62	0.84
SD	1.071	2.499	0.920	0.656	2.367	1.864	2.069	1.684
Median	4.64	-0.36	6.23	1.43	8.21	0.54	6.30	0.71
Q1, Q3	3.57, 5.71	-2.86, 2.14	6.07, 6.43	0.36, 1.43	5.00, 9.28	-0.36, 2.40	5.00, 8.57	-0.36, 2.14
Min, Max	3.6, 5.7	-2.9, 2.1	4.6, 7.5	0.2, 1.8	3.6, 10.7	-1.4, 3.9	3.6, 10.7	-2.9, 3.9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urea Nitrogen (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	4.52	-0.48	5.01	0.07	5.45	0.15	5.13	-0.01
SD	1.148	1.610	0.516	0.821	1.545	1.026	1.229	1.052
Median	5.00	-0.36	5.18	-0.00	5.00	0.70	5.00	0.18
Q1, Q3	3.21, 5.36	-2.14, 1.07	4.64, 5.38	-0.58, 0.71	4.64, 7.10	-1.07, 1.07	4.64, 5.40	-0.80, 1.07
Min, Max	3.2, 5.4	-2.1, 1.1	4.3, 5.4	-0.8, 1.1	2.9, 7.1	-1.4, 1.1	2.9, 7.1	-2.1, 1.1
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	4.82	1.07	5.91	0.97	5.81	-0.58	5.70	0.10
SD	0.252	0.000	0.677	1.196	1.929	1.647	1.501	1.566
Median	4.82	1.07	6.11	1.07	6.36	-0.48	6.18	0.13
Q1, Q3	4.64, 5.00	1.07, 1.07	5.40, 6.43	-0.02, 1.96	4.64, 7.05	-1.79, 0.49	5.00, 6.43	-0.60, 1.07
Min, Max	4.6, 5.0	1.1, 1.1	5.0, 6.4	-0.4, 2.1	2.5, 7.9	-2.9, 1.8	2.5, 7.9	-2.9, 2.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urea Nitrogen (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	5.00	1.43	5.45	0.51	6.77	0.47	6.13	0.57
SD	NC	NC	0.851	0.711	2.292	1.145	1.844	0.943
Median	5.00	1.43	5.71	0.36	7.10	0.54	6.07	0.71
Q1, Q3	5.00, 5.00	1.43, 1.43	4.82, 6.08	-0.05, 1.07	4.64, 8.93	0.30, 0.71	4.64, 7.50	0.00, 1.43
Min, Max	5.0, 5.0	1.4, 1.4	4.3, 6.1	-0.1, 1.4	3.6, 9.3	-1.4, 2.1	3.6, 9.3	-1.4, 2.1
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	5.00	1.43	6.07	1.13	12.60	5.61	9.23	3.40
SD	NC	NC	1.650	1.276	13.708	12.869	9.856	8.921
Median	5.00	1.43	6.07	0.83	6.43	0.36	5.71	0.71
Q1, Q3	5.00, 5.00	1.43, 1.43	4.64, 7.50	0.18, 2.08	4.80, 10.35	-0.36, 1.07	4.64, 7.50	0.00, 1.43
Min, Max	5.0, 5.0	1.4, 1.4	4.6, 7.5	0.0, 2.9	4.6, 36.8	-1.6, 28.6	4.6, 36.8	-1.6, 28.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urea Nitrogen (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	6.53	1.59	7.55	0.56	7.10	1.02
SD	NC	NC	1.941	2.042	2.088	1.707	1.969	1.822
Median	NC	NC	5.93	0.71	7.14	1.07	6.50	0.71
Q1, Q3	NC, NC	NC, NC	5.18, 7.89	0.51, 2.68	6.43, 9.28	-0.71, 1.07	5.36, 9.28	0.30, 1.07
Min, Max	NC, NC	NC, NC	5.0, 9.3	0.3, 4.6	4.9, 10.0	-1.5, 2.9	4.9, 10.0	-1.5, 4.6
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	5.36	0.83	8.45	0.36	6.90	0.60
SD	NC	NC	0.714	0.743	1.761	1.237	2.078	0.949
Median	NC	NC	5.36	1.07	9.28	1.07	6.25	1.07
Q1, Q3	NC, NC	NC, NC	4.64, 6.07	0.00, 1.43	6.43, 9.64	-1.07, 1.07	5.36, 9.28	0.00, 1.07
Min, Max	NC, NC	NC, NC	4.6, 6.1	0.0, 1.4	6.4, 9.6	-1.1, 1.1	4.6, 9.6	-1.1, 1.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urea Nitrogen (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	5.00	0.48	8.75	-0.71	6.50	-0.00
SD	NC	NC	0.714	0.545	0.252	2.019	2.118	1.262
Median	NC	NC	5.00	0.36	8.75	-0.71	5.71	0.36
Q1, Q3	NC, NC	NC, NC	4.28, 5.71	0.00, 1.07	8.57, 8.93	-2.14, 0.71	5.00, 8.57	0.00, 0.71
Min, Max	NC, NC	NC, NC	4.3, 5.7	0.0, 1.1	8.6, 8.9	-2.1, 0.7	4.3, 8.9	-2.1, 1.1
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	5.00	0.71	9.46	0.00	7.97	0.24
SD	NC	NC	NC	NC	0.252	2.019	2.583	1.486
Median	NC	NC	5.00	0.71	9.46	0.00	9.28	0.71
Q1, Q3	NC, NC	NC, NC	5.00, 5.00	0.71, 0.71	9.28, 9.64	-1.43, 1.43	5.00, 9.64	-1.43, 1.43
Min, Max	NC, NC	NC, NC	5.0, 5.0	0.7, 0.7	9.3, 9.6	-1.4, 1.4	5.0, 9.6	-1.4, 1.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urea Nitrogen (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	3.93	-0.36	9.64	1.43	6.78	0.54
SD	NC	NC	NC	NC	NC	NC	4.039	1.262
Median	NC	NC	3.93	-0.36	9.64	1.43	6.78	0.54
Q1, Q3	NC, NC	NC, NC	3.93, 3.93	-0.36, -0.36	9.64, 9.64	1.43, 1.43	3.93, 9.64	-0.36, 1.43
Min, Max	NC, NC	NC, NC	3.9, 3.9	-0.4, -0.4	9.6, 9.6	1.4, 1.4	3.9, 9.6	-0.4, 1.4
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	4.64	0.36	9.64	1.43	7.14	0.89
SD	NC	NC	NC	NC	NC	NC	3.534	0.757
Median	NC	NC	4.64	0.36	9.64	1.43	7.14	0.89
Q1, Q3	NC, NC	NC, NC	4.64, 4.64	0.36, 0.36	9.64, 9.64	1.43, 1.43	4.64, 9.64	0.36, 1.43
Min, Max	NC, NC	NC, NC	4.6, 4.6	0.4, 0.4	9.6, 9.6	1.4, 1.4	4.6, 9.6	0.4, 1.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urea Nitrogen (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	5.71	1.43	10.00	1.79	7.85	1.61
SD	NC	NC	NC	NC	NC	NC	3.029	0.252
Median	NC	NC	5.71	1.43	10.00	1.79	7.85	1.61
Q1, Q3	NC, NC	NC, NC	5.71, 5.71	1.43, 1.43	10.00, 10.00	1.79, 1.79	5.71, 10.00	1.43, 1.79
Min, Max	NC, NC	NC, NC	5.7, 5.7	1.4, 1.4	10.0, 10.0	1.8, 1.8	5.7, 10.0	1.4, 1.8
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	5.36	1.07	NC	NC	5.36	1.07
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	5.36	1.07	NC	NC	5.36	1.07
Q1, Q3	NC, NC	NC, NC	5.36, 5.36	1.07, 1.07	NC, NC	NC, NC	5.36, 5.36	1.07, 1.07
Min, Max	NC, NC	NC, NC	5.4, 5.4	1.1, 1.1	NC, NC	NC, NC	5.4, 5.4	1.1, 1.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urea Nitrogen (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.28	0.00	NC	NC	4.28	0.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.28	0.00	NC	NC	4.28	0.00
Q1, Q3	NC, NC	NC, NC	4.28, 4.28	0.00, 0.00	NC, NC	NC, NC	4.28, 4.28	0.00, 0.00
Min, Max	NC, NC	NC, NC	4.3, 4.3	0.0, 0.0	NC, NC	NC, NC	4.3, 4.3	0.0, 0.0
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.64	0.36	NC	NC	4.64	0.36
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.64	0.36	NC	NC	4.64	0.36
Q1, Q3	NC, NC	NC, NC	4.64, 4.64	0.36, 0.36	NC, NC	NC, NC	4.64, 4.64	0.36, 0.36
Min, Max	NC, NC	NC, NC	4.6, 4.6	0.4, 0.4	NC, NC	NC, NC	4.6, 4.6	0.4, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urea Nitrogen (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	6.55	1.55	6.09	1.15	6.90	0.38	6.62	0.82
SD	1.610	2.679	1.893	2.274	2.553	1.149	2.127	1.746
Median	6.43	1.43	5.23	0.71	5.83	0.71	5.60	0.71
Q1, Q3	5.00, 8.21	-1.07, 4.28	5.05, 7.14	-0.37, 2.68	5.18, 8.75	-0.25, 1.07	5.00, 8.21	-0.80, 1.43
Min, Max	5.0, 8.2	-1.1, 4.3	5.0, 8.9	-1.1, 4.3	4.3, 11.4	-1.8, 1.8	4.3, 11.4	-1.8, 4.3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Creatinine (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	66.3		93.9		90.8		87.2	
SD	5.10		20.68		41.59		31.94	
Median	66.3		106.1		70.7		70.7	
Q1, Q3	61.9, 70.7		82.2, 106.1		67.0, 106.1		67.0, 106.1	
Min, Max	62, 71		54, 113		53, 191		53, 191	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	67.5	2.7	93.1	1.2	209.8	119.0	150.5	63.4
SD	9.70	13.02	21.60	5.77	363.99	359.99	265.68	261.63
Median	61.9	0.0	93.6	1.8	88.7	6.6	88.4	1.8
Q1, Q3	61.9, 78.7	-8.8, 16.8	84.0, 114.9	0.0, 3.5	61.9, 129.1	0.0, 17.7	61.9, 114.9	0.0, 12.4
Min, Max	62, 79	-9, 17	57, 115	-9, 9	53, 1238	-14, 1143	53, 1238	-14, 1143

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Creatinine (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	63.9	-0.9	92.6	-5.3	87.3	0.1	83.8	-1.6
SD	3.57	7.55	16.01	8.78	42.76	5.72	32.03	6.90
Median	61.9	0.0	89.2	-2.7	70.7	0.0	70.7	0.0
Q1, Q3	61.9, 68.1	-8.8, 6.2	82.7, 102.5	-11.5, 0.9	69.0, 98.1	0.0, 3.5	68.1, 90.0	-5.3, 1.8
Min, Max	62, 68	-9, 6	77, 115	-18, 2	53, 179	-11, 7	53, 179	-18, 7
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	66.3	4.4	102.6	4.7	90.6	-0.7	90.6	1.6
SD	6.25	6.25	23.42	11.45	47.26	11.26	38.31	10.44
Median	66.3	4.4	95.5	1.3	70.4	1.0	77.8	1.0
Q1, Q3	61.9, 70.7	0.0, 8.8	84.9, 120.2	-2.5, 11.9	65.4, 100.3	-3.1, 7.5	69.0, 101.7	0.0, 8.0
Min, Max	62, 71	0, 9	85, 134	-5, 21	53, 200	-26, 9	53, 200	-26, 21

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Creatinine (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	8928.4	8866.5	103.2	5.3	99.4	4.5	903.4	810.4
SD	NC	NC	21.05	6.89	64.03	19.96	2662.00	2671.95
Median	8928.4	8866.5	102.5	4.4	76.3	4.4	90.0	8.8
Q1, Q3	8928.4, 8928.4	8866.5, 8866.5	85.7, 120.7	-0.4, 11.1	65.4, 99.0	-2.7, 11.0	73.0, 126.4	-0.9, 13.3
Min, Max	8928, 8928	8867, 8867	81, 126	-1, 13	53, 226	-26, 35	53, 8928	-26, 8867
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	78.7	16.8	99.8	1.9	96.4	-3.9	96.0	0.5
SD	NC	NC	18.62	5.83	49.19	16.03	35.08	12.90
Median	78.7	16.8	100.5	2.5	88.4	0.0	91.7	0.5
Q1, Q3	78.7, 78.7	16.8, 16.8	86.0, 113.6	-2.7, 6.5	63.0, 99.9	-13.3, 1.0	76.9, 106.1	-5.3, 8.0
Min, Max	79, 79	17, 17	77, 121	-5, 8	53, 178	-25, 18	53, 178	-25, 18

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Creatinine (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	109.8	11.9	98.5	-1.8	103.5	4.3
SD	NC	NC	26.99	16.15	55.60	10.53	43.06	14.33
Median	NC	NC	106.4	6.2	70.7	0.0	90.0	1.8
Q1, Q3	NC, NC	NC, NC	87.4, 132.2	1.3, 22.5	62.0, 105.2	0.0, 1.8	70.7, 122.9	0.0, 8.8
Min, Max	NC, NC	NC, NC	85, 141	0, 35	62, 193	-19, 9	62, 193	-19, 35
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	100.5	0.0	126.1	-2.7	113.3	-1.3
SD	NC	NC	23.06	7.07	59.08	2.65	42.50	4.99
Median	NC	NC	106.1	0.0	119.3	-2.7	112.7	-1.3
Q1, Q3	NC, NC	NC, NC	75.1, 120.2	-7.1, 7.1	70.7, 188.3	-5.3, 0.0	75.1, 120.2	-5.3, 0.0
Min, Max	NC, NC	NC, NC	75, 120	-7, 7	71, 188	-5, 0	71, 188	-7, 7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Creatinine (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	101.4	0.9	143.7	-14.1	118.3	-5.1
SD	NC	NC	24.25	8.97	59.38	12.50	41.38	12.13
Median	NC	NC	114.9	2.7	143.7	-14.1	114.9	-5.3
Q1, Q3	NC, NC	NC, NC	73.4, 115.8	-8.8, 8.8	101.7, 185.6	-23.0, -5.3	101.7, 115.8	-8.8, 2.7
Min, Max	NC, NC	NC, NC	73, 116	-9, 9	102, 186	-23, -5	73, 186	-23, 9
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	108.7	-4.4	150.3	-7.5	136.4	-6.5
SD	NC	NC	NC	NC	40.01	6.88	37.09	5.18
Median	NC	NC	108.7	-4.4	150.3	-7.5	122.0	-4.4
Q1, Q3	NC, NC	NC, NC	108.7, 108.7	-4.4, -4.4	122.0, 178.6	-12.4, -2.7	108.7, 178.6	-12.4, -2.7
Min, Max	NC, NC	NC, NC	109, 109	-4, -4	122, 179	-12, -3	109, 179	-12, -3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Creatinine (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	122.9	9.7	194.5	3.5	158.7	6.6
SD	NC	NC	NC	NC	NC	NC	50.63	4.38
Median	NC	NC	122.9	9.7	194.5	3.5	158.7	6.6
Q1, Q3	NC, NC	NC, NC	122.9, 122.9	9.7, 9.7	194.5, 194.5	3.5, 3.5	122.9, 194.5	3.5, 9.7
Min, Max	NC, NC	NC, NC	123, 123	10, 10	194, 194	4, 4	123, 194	4, 10
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	118.5	5.3	178.6	-12.4	148.5	-3.5
SD	NC	NC	NC	NC	NC	NC	42.51	12.50
Median	NC	NC	118.5	5.3	178.6	-12.4	148.5	-3.5
Q1, Q3	NC, NC	NC, NC	118.5, 118.5	5.3, 5.3	178.6, 178.6	-12.4, -12.4	118.5, 178.6	-12.4, 5.3
Min, Max	NC, NC	NC, NC	118, 118	5, 5	179, 179	-12, -12	118, 179	-12, 5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Creatinine (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	113.2	0.0	191.8	0.9	152.5	0.4
SD	NC	NC	NC	NC	NC	NC	55.63	0.63
Median	NC	NC	113.2	0.0	191.8	0.9	152.5	0.4
Q1, Q3	NC, NC	NC, NC	113.2, 113.2	0.0, 0.0	191.8, 191.8	0.9, 0.9	113.2, 191.8	0.0, 0.9
Min, Max	NC, NC	NC, NC	113, 113	0, 0	192, 192	1, 1	113, 192	0, 1
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	114.9	1.8	NC	NC	114.9	1.8
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	114.9	1.8	NC	NC	114.9	1.8
Q1, Q3	NC, NC	NC, NC	114.9, 114.9	1.8, 1.8	NC, NC	NC, NC	114.9, 114.9	1.8, 1.8
Min, Max	NC, NC	NC, NC	115, 115	2, 2	NC, NC	NC, NC	115, 115	2, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Creatinine (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	109.6	-3.5	NC	NC	109.6	-3.5
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	109.6	-3.5	NC	NC	109.6	-3.5
Q1, Q3	NC, NC	NC, NC	109.6, 109.6	-3.5, -3.5	NC, NC	NC, NC	109.6, 109.6	-3.5, -3.5
Min, Max	NC, NC	NC, NC	110, 110	-4, -4	NC, NC	NC, NC	110, 110	-4, -4
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	118.5	5.3	NC	NC	118.5	5.3
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	118.5	5.3	NC	NC	118.5	5.3
Q1, Q3	NC, NC	NC, NC	118.5, 118.5	5.3, 5.3	NC, NC	NC, NC	118.5, 118.5	5.3, 5.3
Min, Max	NC, NC	NC, NC	118, 118	5, 5	NC, NC	NC, NC	118, 118	5, 5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Creatinine (umol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	70.4	5.6	99.5	1.6	90.2	-1.5	88.7	0.8
SD	8.40	13.12	27.73	17.11	46.27	11.37	36.76	12.65
Median	70.7	8.8	97.8	-3.8	78.2	0.4	78.7	0.0
Q1, Q3	61.9, 78.7	-8.8, 16.8	77.4, 121.6	-8.7, 11.9	57.5, 103.9	-11.9, 4.8	61.9, 109.6	-8.8, 8.8
Min, Max	62, 79	-9, 17	70, 133	-12, 27	51, 192	-16, 18	51, 192	-16, 27

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	1		4		6		11	
Mean	9.54		6.02		5.41		6.01	
SD	NC		0.794		0.683		1.372	
Median	9.54		5.76		5.47		5.64	
Q1, Q3	9.54, 9.54		5.46, 6.57		5.28, 5.94		5.30, 6.12	
Min, Max	9.5, 9.5		5.4, 7.1		4.2, 6.1		4.2, 9.5	
Cycle 1 Day 6								
Nx	1	1	3	3	6	6	10	10
Mean	8.28	-1.26	6.16	0.14	5.32	-0.10	5.87	-0.14
SD	NC	NC	0.997	0.567	0.818	0.252	1.213	0.523
Median	8.28	-1.26	6.30	-0.06	5.61	-0.09	5.94	-0.12
Q1, Q3	8.28, 8.28	-1.26, -1.26	5.10, 7.08	-0.30, 0.78	4.90, 5.94	-0.30, 0.00	5.10, 6.30	-0.30, 0.00
Min, Max	8.3, 8.3	-1.3, -1.3	5.1, 7.1	-0.3, 0.8	3.9, 5.9	-0.4, 0.3	3.9, 8.3	-1.3, 0.8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	1	1	2	2	4	4	7	7
Mean	7.08	-2.46	6.33	0.00	5.46	0.08	5.94	-0.31
SD	NC	NC	0.891	0.255	0.946	0.780	1.000	1.103
Median	7.08	-2.46	6.33	0.00	5.58	-0.21	5.70	-0.18
Q1, Q3	7.08, 7.08	-2.46, -2.46	5.70, 6.96	-0.18, 0.18	4.83, 6.09	-0.45, 0.60	5.46, 6.96	-0.48, 0.18
Min, Max	7.1, 7.1	-2.5, -2.5	5.7, 7.0	-0.2, 0.2	4.2, 6.5	-0.5, 1.2	4.2, 7.1	-2.5, 1.2
Cycle 2 Day 1								
Nx	1	1	3	3	6	6	10	10
Mean	7.68	-1.86	6.39	0.37	5.55	0.13	6.01	0.00
SD	NC	NC	1.537	0.681	0.655	0.435	1.124	0.806
Median	7.68	-1.86	6.12	0.60	5.73	0.20	5.94	0.20
Q1, Q3	7.68, 7.68	-1.86, -1.86	5.00, 8.04	-0.40, 0.90	5.46, 6.00	-0.24, 0.42	5.46, 6.12	-0.40, 0.60
Min, Max	7.7, 7.7	-1.9, -1.9	5.0, 8.0	-0.4, 0.9	4.3, 6.1	-0.5, 0.7	4.3, 8.0	-1.9, 0.9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	2	2	4	4	7	7
Mean	5.58	-3.96	6.48	0.15	5.55	0.24	5.82	-0.39
SD	NC	NC	0.849	0.297	0.671	0.404	0.742	1.606
Median	5.58	-3.96	6.48	0.15	5.70	0.38	5.76	0.36
Q1, Q3	5.58, 5.58	-3.96, -3.96	5.88, 7.08	-0.06, 0.36	5.12, 5.97	0.00, 0.47	5.58, 6.18	-0.36, 0.40
Min, Max	5.6, 5.6	-4.0, -4.0	5.9, 7.1	-0.1, 0.4	4.6, 6.2	-0.4, 0.5	4.6, 7.1	-4.0, 0.5
Cycle 5 Day 1								
Nx	1	1	3	3	3	3	7	7
Mean	5.94	-3.60	6.38	0.36	5.59	0.27	5.98	-0.24
SD	NC	NC	0.764	0.240	0.873	0.142	0.777	1.490
Median	5.94	-3.60	6.00	0.36	5.94	0.30	5.94	0.30
Q1, Q3	5.94, 5.94	-3.60, -3.60	5.88, 7.26	0.12, 0.60	4.60, 6.24	0.12, 0.40	5.88, 6.24	0.12, 0.40
Min, Max	5.9, 5.9	-3.6, -3.6	5.9, 7.3	0.1, 0.6	4.6, 6.2	0.1, 0.4	4.6, 7.3	-3.6, 0.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	2	2	3	3	5	5
Mean	NC	NC	6.81	0.48	5.58	0.26	6.07	0.35
SD	NC	NC	0.467	0.679	0.937	0.183	0.973	0.383
Median	NC	NC	6.81	0.48	6.06	0.30	6.18	0.30
Q1, Q3	NC, NC	NC, NC	6.48, 7.14	0.00, 0.96	4.50, 6.18	0.06, 0.42	6.06, 6.48	0.06, 0.42
Min, Max	NC, NC	NC, NC	6.5, 7.1	0.0, 1.0	4.5, 6.2	0.1, 0.4	4.5, 7.1	0.0, 1.0
Cycle 9 Day 1								
Nx	0	0	2	2	2	2	4	4
Mean	NC	NC	6.06	-0.27	5.76	-0.12	5.91	-0.20
SD	NC	NC	0.085	1.230	0.170	0.509	0.205	0.774
Median	NC	NC	6.06	-0.27	5.76	-0.12	5.94	-0.12
Q1, Q3	NC, NC	NC, NC	6.00, 6.12	-1.14, 0.60	5.64, 5.88	-0.48, 0.24	5.76, 6.06	-0.81, 0.42
Min, Max	NC, NC	NC, NC	6.0, 6.1	-1.1, 0.6	5.6, 5.9	-0.5, 0.2	5.6, 6.1	-1.1, 0.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	2	2	2	2	4	4
Mean	NC	NC	6.63	0.30	5.88	0.00	6.26	0.15
SD	NC	NC	0.042	1.188	0.000	0.339	0.434	0.734
Median	NC	NC	6.63	0.30	5.88	0.00	6.24	0.00
Q1, Q3	NC, NC	NC, NC	6.60, 6.66	-0.54, 1.14	5.88, 5.88	-0.24, 0.24	5.88, 6.63	-0.39, 0.69
Min, Max	NC, NC	NC, NC	6.6, 6.7	-0.5, 1.1	5.9, 5.9	-0.2, 0.2	5.9, 6.7	-0.5, 1.1
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	5.88	0.36	5.58	-0.30	5.68	-0.08
SD	NC	NC	NC	NC	0.255	0.085	0.250	0.386
Median	NC	NC	5.88	0.36	5.58	-0.30	5.76	-0.24
Q1, Q3	NC, NC	NC, NC	5.88, 5.88	0.36, 0.36	5.40, 5.76	-0.36, -0.24	5.40, 5.88	-0.36, 0.36
Min, Max	NC, NC	NC, NC	5.9, 5.9	0.4, 0.4	5.4, 5.8	-0.4, -0.2	5.4, 5.9	-0.4, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	6.24	0.72	5.70	-0.42	5.97	0.15
SD	NC	NC	NC	NC	NC	NC	0.382	0.806
Median	NC	NC	6.24	0.72	5.70	-0.42	5.97	0.15
Q1, Q3	NC, NC	NC, NC	6.24, 6.24	0.72, 0.72	5.70, 5.70	-0.42, -0.42	5.70, 6.24	-0.42, 0.72
Min, Max	NC, NC	NC, NC	6.2, 6.2	0.7, 0.7	5.7, 5.7	-0.4, -0.4	5.7, 6.2	-0.4, 0.7
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	5.94	0.42	5.58	-0.54	5.76	-0.06
SD	NC	NC	NC	NC	NC	NC	0.255	0.679
Median	NC	NC	5.94	0.42	5.58	-0.54	5.76	-0.06
Q1, Q3	NC, NC	NC, NC	5.94, 5.94	0.42, 0.42	5.58, 5.58	-0.54, -0.54	5.58, 5.94	-0.54, 0.42
Min, Max	NC, NC	NC, NC	5.9, 5.9	0.4, 0.4	5.6, 5.6	-0.5, -0.5	5.6, 5.9	-0.5, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	5.64	0.12	5.70	-0.42	5.67	-0.15
SD	NC	NC	NC	NC	NC	NC	0.042	0.382
Median	NC	NC	5.64	0.12	5.70	-0.42	5.67	-0.15
Q1, Q3	NC, NC	NC, NC	5.64, 5.64	0.12, 0.12	5.70, 5.70	-0.42, -0.42	5.64, 5.70	-0.42, 0.12
Min, Max	NC, NC	NC, NC	5.6, 5.6	0.1, 0.1	5.7, 5.7	-0.4, -0.4	5.6, 5.7	-0.4, 0.1
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	5.82	0.30	NC	NC	5.82	0.30
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	5.82	0.30	NC	NC	5.82	0.30
Q1, Q3	NC, NC	NC, NC	5.82, 5.82	0.30, 0.30	NC, NC	NC, NC	5.82, 5.82	0.30, 0.30
Min, Max	NC, NC	NC, NC	5.8, 5.8	0.3, 0.3	NC, NC	NC, NC	5.8, 5.8	0.3, 0.3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	6.00	0.48	NC	NC	6.00	0.48
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	6.00	0.48	NC	NC	6.00	0.48
Q1, Q3	NC, NC	NC, NC	6.00, 6.00	0.48, 0.48	NC, NC	NC, NC	6.00, 6.00	0.48, 0.48
Min, Max	NC, NC	NC, NC	6.0, 6.0	0.5, 0.5	NC, NC	NC, NC	6.0, 6.0	0.5, 0.5
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	6.06	0.54	NC	NC	6.06	0.54
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	6.06	0.54	NC	NC	6.06	0.54
Q1, Q3	NC, NC	NC, NC	6.06, 6.06	0.54, 0.54	NC, NC	NC, NC	6.06, 6.06	0.54, 0.54
Min, Max	NC, NC	NC, NC	6.1, 6.1	0.5, 0.5	NC, NC	NC, NC	6.1, 6.1	0.5, 0.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Fasting Glucose (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	1	1	2	2	5	5	8	8
Mean	5.94	-3.60	6.12	-0.21	5.15	-0.29	5.49	-0.69
SD	NC	NC	0.170	0.976	0.480	0.397	0.601	1.271
Median	5.94	-3.60	6.12	-0.21	5.28	-0.42	5.58	-0.45
Q1, Q3	5.94, 5.94	-3.60, -3.60	6.00, 6.24	-0.90, 0.48	4.70, 5.46	-0.48, -0.36	4.99, 5.97	-0.75, 0.02
Min, Max	5.9, 5.9	-3.6, -3.6	6.0, 6.2	-0.9, 0.5	4.6, 5.7	-0.6, 0.4	4.6, 6.2	-3.6, 0.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Non-Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value			Value		Value		Value	
Baseline								
Nx	4		4		4		12	
Mean	7.92		7.01		7.65		7.53	
SD	1.716		2.253		2.067		1.874	
Median	8.13		6.33		6.87		6.84	
Q1, Q3	6.51, 9.33		5.61, 8.40		6.24, 9.06		6.18, 9.33	
Min, Max	5.9, 9.5		5.1, 10.3		6.2, 10.6		5.1, 10.6	
Cycle 1 Day 6								
Nx	2	2	2	2	4	4	8	8
Mean	8.01	-0.12	8.58	2.25	7.86	0.21	8.08	0.64
SD	2.249	0.849	0.085	0.382	1.787	0.931	1.481	1.228
Median	8.01	-0.12	8.58	2.25	7.20	0.42	7.86	0.72
Q1, Q3	6.42, 9.60	-0.72, 0.48	8.52, 8.64	1.98, 2.52	6.87, 8.85	-0.54, 0.96	6.87, 9.12	-0.42, 1.47
Min, Max	6.4, 9.6	-0.7, 0.5	8.5, 8.6	2.0, 2.5	6.5, 10.5	-1.0, 1.0	6.4, 10.5	-1.0, 2.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Non-Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	2	2	1	1	4	3	7	6
Mean	9.54	1.41	6.12	-0.42	6.56	0.18	7.35	0.49
SD	0.170	1.230	NC	NC	0.643	0.600	1.576	1.004
Median	9.54	1.41	6.12	-0.42	6.72	0.18	7.02	0.36
Q1, Q3	9.42, 9.66	0.54, 2.28	6.12, 6.12	-0.42, -0.42	6.06, 7.05	-0.42, 0.78	6.12, 9.42	-0.42, 0.78
Min, Max	9.4, 9.7	0.5, 2.3	6.1, 6.1	-0.4, -0.4	5.7, 7.1	-0.4, 0.8	5.7, 9.7	-0.4, 2.3
Cycle 2 Day 1								
Nx	1	1	1	1	3	2	5	4
Mean	6.90	-0.24	5.58	-0.96	6.04	-0.66	6.12	-0.63
SD	NC	NC	NC	NC	0.296	0.933	0.523	0.615
Median	6.90	-0.24	5.58	-0.96	6.18	-0.66	6.18	-0.60
Q1, Q3	6.90, 6.90	-0.24, -0.24	5.58, 5.58	-0.96, -0.96	5.70, 6.24	-1.32, 0.00	5.70, 6.24	-1.14, -0.12
Min, Max	6.9, 6.9	-0.2, -0.2	5.6, 5.6	-1.0, -1.0	5.7, 6.2	-1.3, 0.0	5.6, 6.9	-1.3, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Non-Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	0	0	2	2	2	2	4	4
Mean	NC	NC	5.11	-0.71	7.05	0.18	6.08	-0.27
SD	NC	NC	1.428	0.410	0.806	0.085	1.467	0.568
Median	NC	NC	5.11	-0.71	7.05	0.18	6.30	-0.15
Q1, Q3	NC, NC	NC, NC	4.10, 6.12	-1.00, -0.42	6.48, 7.62	0.12, 0.24	5.11, 7.05	-0.71, 0.18
Min, Max	NC, NC	NC, NC	4.1, 6.1	-1.0, -0.4	6.5, 7.6	0.1, 0.2	4.1, 7.6	-1.0, 0.2
Cycle 5 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	5.40	-1.14	6.24	-0.63	5.96	-0.80
SD	NC	NC	NC	NC	0.933	1.824	0.819	1.323
Median	NC	NC	5.40	-1.14	6.24	-0.63	5.58	-1.14
Q1, Q3	NC, NC	NC, NC	5.40, 5.40	-1.14, -1.14	5.58, 6.90	-1.92, 0.66	5.40, 6.90	-1.92, 0.66
Min, Max	NC, NC	NC, NC	5.4, 5.4	-1.1, -1.1	5.6, 6.9	-1.9, 0.7	5.4, 6.9	-1.9, 0.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Non-Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	2	2	2	2	4	4
Mean	NC	NC	6.02	0.20	6.90	0.03	6.46	0.12
SD	NC	NC	1.160	0.141	0.509	0.382	0.890	0.255
Median	NC	NC	6.02	0.20	6.90	0.03	6.69	0.20
Q1, Q3	NC, NC	NC, NC	5.20, 6.84	0.10, 0.30	6.54, 7.26	-0.24, 0.30	5.87, 7.05	-0.07, 0.30
Min, Max	NC, NC	NC, NC	5.2, 6.8	0.1, 0.3	6.5, 7.3	-0.2, 0.3	5.2, 7.3	-0.2, 0.3
Cycle 9 Day 1								
Nx	0	0	1	1	2	1	3	2
Mean	NC	NC	6.12	-0.42	6.33	0.36	6.26	-0.03
SD	NC	NC	NC	NC	0.382	NC	0.296	0.552
Median	NC	NC	6.12	-0.42	6.33	0.36	6.12	-0.03
Q1, Q3	NC, NC	NC, NC	6.12, 6.12	-0.42, -0.42	6.06, 6.60	0.36, 0.36	6.06, 6.60	-0.42, 0.36
Min, Max	NC, NC	NC, NC	6.1, 6.1	-0.4, -0.4	6.1, 6.6	0.4, 0.4	6.1, 6.6	-0.4, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Non-Fasting Glucose (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	6.78	0.24	NC	NC	6.78	0.24
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	6.78	0.24	NC	NC	6.78	0.24
Q1, Q3	NC, NC	NC, NC	6.78, 6.78	0.24, 0.24	NC, NC	NC, NC	6.78, 6.78	0.24, 0.24
Min, Max	NC, NC	NC, NC	6.8, 6.8	0.2, 0.2	NC, NC	NC, NC	6.8, 6.8	0.2, 0.2
Cycle 13 Day 1								
Nx	0	0	0	0	1	0	1	0
Mean	NC	NC	NC	NC	6.06	NC	6.06	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	NC	NC	6.06	NC	6.06	NC
Q1, Q3	NC, NC	NC, NC	NC, NC	NC, NC	6.06, 6.06	NC, NC	6.06, 6.06	NC, NC
Min, Max	NC, NC	NC, NC	NC, NC	NC, NC	6.1, 6.1	NC, NC	6.1, 6.1	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Non-Fasting Glucose (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	2	2	2	2	3	2	7	6
Mean	8.10	-0.03	5.37	-0.45	5.96	-0.51	6.40	-0.33
SD	1.527	0.127	0.806	0.212	0.781	1.400	1.454	0.677
Median	8.10	-0.03	5.37	-0.45	6.00	-0.51	6.00	-0.21
Q1, Q3	7.02, 9.18	-0.12, 0.06	4.80, 5.94	-0.60, -0.30	5.16, 6.72	-1.50, 0.48	5.16, 7.02	-0.60, 0.06
Min, Max	7.0, 9.2	-0.1, 0.1	4.8, 5.9	-0.6, -0.3	5.2, 6.7	-1.5, 0.5	4.8, 9.2	-1.5, 0.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bicarbonate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	27.00		27.00		27.78		27.37	
SD	2.944		3.162		3.479		3.147	
Median	26.50		26.00		27.80		27.00	
Q1, Q3	25.00, 29.00		24.00, 29.00		24.00, 31.20		24.00, 29.00	
Min, Max	24.0, 31.0		23.0, 32.0		23.0, 33.0		23.0, 33.0	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	25.00	-0.67	26.17	-1.50	26.49	-1.29	26.15	-1.26
SD	1.732	2.082	3.601	2.429	2.989	2.919	2.947	2.542
Median	24.00	0.00	27.00	-2.50	25.95	-0.85	26.90	-1.00
Q1, Q3	24.00, 27.00	-3.00, 1.00	23.00, 28.00	-3.00, 1.00	24.00, 29.00	-3.00, 1.00	24.00, 28.00	-3.00, 1.00
Min, Max	24.0, 27.0	-3.0, 1.0	21.0, 31.0	-4.0, 2.0	23.0, 31.0	-7.2, 3.0	21.0, 31.0	-7.2, 3.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bicarbonate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	26.33	0.67	28.00	1.00	26.69	-0.11	26.99	0.37
SD	1.528	0.577	2.449	0.000	2.650	4.238	2.334	2.934
Median	26.00	1.00	28.50	1.00	28.00	0.00	27.50	1.00
Q1, Q3	25.00, 28.00	0.00, 1.00	26.00, 30.00	1.00, 1.00	23.00, 28.00	-5.00, 4.00	25.00, 28.00	0.00, 1.00
Min, Max	25.0, 28.0	0.0, 1.0	25.0, 30.0	1.0, 1.0	23.0, 29.8	-6.0, 5.0	23.0, 30.0	-6.0, 5.0
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	26.00	-0.50	28.25	1.25	25.98	-0.63	26.63	-0.07
SD	0.000	0.707	3.304	1.500	2.624	4.241	2.713	3.316
Median	26.00	-0.50	28.50	1.00	26.50	0.00	26.50	0.00
Q1, Q3	26.00, 26.00	-1.00, 0.00	26.00, 30.50	0.00, 2.50	24.60, 27.50	-4.00, 2.50	25.00, 28.00	-1.00, 2.00
Min, Max	26.0, 26.0	-1.0, 0.0	24.0, 32.0	0.0, 3.0	21.0, 29.6	-7.0, 5.0	21.0, 32.0	-7.0, 5.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bicarbonate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	26.00	0.00	26.75	-0.25	27.12	0.85	26.88	0.37
SD	NC	NC	2.630	0.957	2.060	2.649	2.077	2.022
Median	26.00	0.00	27.50	-0.50	27.00	1.00	27.00	0.00
Q1, Q3	26.00, 26.00	0.00, 0.00	25.00, 28.50	-1.00, 0.50	25.00, 29.00	-2.00, 2.10	25.00, 29.00	-1.00, 1.00
Min, Max	26.0, 26.0	0.0, 0.0	23.0, 29.0	-1.0, 1.0	25.0, 29.7	-2.0, 5.0	23.0, 29.7	-2.0, 5.0
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	27.00	1.00	27.25	0.25	27.18	0.46	27.19	0.43
SD	NC	NC	2.754	0.500	4.285	3.893	3.270	2.621
Median	27.00	1.00	27.50	0.00	25.00	1.00	26.50	0.50
Q1, Q3	27.00, 27.00	1.00, 1.00	25.00, 29.50	0.00, 0.50	24.00, 29.00	-2.00, 1.00	24.00, 29.00	0.00, 1.00
Min, Max	27.0, 27.0	1.0, 1.0	24.0, 30.0	0.0, 1.0	24.0, 33.9	-4.0, 6.3	24.0, 33.9	-4.0, 6.3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bicarbonate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	27.75	0.75	26.36	-0.36	26.98	0.13
SD	NC	NC	4.992	4.113	3.968	4.213	4.214	3.945
Median	NC	NC	29.00	0.00	26.00	0.00	27.00	0.00
Q1, Q3	NC, NC	NC, NC	24.00, 31.50	-2.50, 4.00	25.00, 28.00	-1.00, 2.00	25.00, 31.00	-2.00, 2.00
Min, Max	NC, NC	NC, NC	21.0, 32.0	-3.0, 6.0	21.0, 31.8	-7.0, 4.2	21.0, 32.0	-7.0, 6.0
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	28.67	2.33	24.33	-1.67	26.50	0.33
SD	NC	NC	1.528	2.082	1.155	3.512	2.665	3.386
Median	NC	NC	29.00	3.00	25.00	-2.00	26.00	1.00
Q1, Q3	NC, NC	NC, NC	27.00, 30.00	0.00, 4.00	23.00, 25.00	-5.00, 2.00	25.00, 29.00	-2.00, 3.00
Min, Max	NC, NC	NC, NC	27.0, 30.0	0.0, 4.0	23.0, 25.0	-5.0, 2.0	23.0, 30.0	-5.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bicarbonate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	27.00	0.67	25.00	0.00	26.20	0.40
SD	NC	NC	1.000	2.309	1.414	4.243	1.483	2.702
Median	NC	NC	27.00	2.00	25.00	0.00	26.00	2.00
Q1, Q3	NC, NC	NC, NC	26.00, 28.00	-2.00, 2.00	24.00, 26.00	-3.00, 3.00	26.00, 27.00	-2.00, 2.00
Min, Max	NC, NC	NC, NC	26.0, 28.0	-2.0, 2.0	24.0, 26.0	-3.0, 3.0	24.0, 28.0	-3.0, 3.0
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	30.00	4.00	24.00	-1.00	26.00	0.67
SD	NC	NC	NC	NC	0.000	2.828	3.464	3.512
Median	NC	NC	30.00	4.00	24.00	-1.00	24.00	1.00
Q1, Q3	NC, NC	NC, NC	30.00, 30.00	4.00, 4.00	24.00, 24.00	-3.00, 1.00	24.00, 30.00	-3.00, 4.00
Min, Max	NC, NC	NC, NC	30.0, 30.0	4.0, 4.0	24.0, 24.0	-3.0, 1.0	24.0, 30.0	-3.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bicarbonate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	29.00	3.00	27.00	4.00	28.00	3.50
SD	NC	NC	NC	NC	NC	NC	1.414	0.707
Median	NC	NC	29.00	3.00	27.00	4.00	28.00	3.50
Q1, Q3	NC, NC	NC, NC	29.00, 29.00	3.00, 3.00	27.00, 27.00	4.00, 4.00	27.00, 29.00	3.00, 4.00
Min, Max	NC, NC	NC, NC	29.0, 29.0	3.0, 3.0	27.0, 27.0	4.0, 4.0	27.0, 29.0	3.0, 4.0
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	30.00	4.00	27.00	4.00	28.50	4.00
SD	NC	NC	NC	NC	NC	NC	2.121	0.000
Median	NC	NC	30.00	4.00	27.00	4.00	28.50	4.00
Q1, Q3	NC, NC	NC, NC	30.00, 30.00	4.00, 4.00	27.00, 27.00	4.00, 4.00	27.00, 30.00	4.00, 4.00
Min, Max	NC, NC	NC, NC	30.0, 30.0	4.0, 4.0	27.0, 27.0	4.0, 4.0	27.0, 30.0	4.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bicarbonate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	32.00	6.00	26.00	3.00	29.00	4.50
SD	NC	NC	NC	NC	NC	NC	4.243	2.121
Median	NC	NC	32.00	6.00	26.00	3.00	29.00	4.50
Q1, Q3	NC, NC	NC, NC	32.00, 32.00	6.00, 6.00	26.00, 26.00	3.00, 3.00	26.00, 32.00	3.00, 6.00
Min, Max	NC, NC	NC, NC	32.0, 32.0	6.0, 6.0	26.0, 26.0	3.0, 3.0	26.0, 32.0	3.0, 6.0
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	29.00	3.00	NC	NC	29.00	3.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	29.00	3.00	NC	NC	29.00	3.00
Q1, Q3	NC, NC	NC, NC	29.00, 29.00	3.00, 3.00	NC, NC	NC, NC	29.00, 29.00	3.00, 3.00
Min, Max	NC, NC	NC, NC	29.0, 29.0	3.0, 3.0	NC, NC	NC, NC	29.0, 29.0	3.0, 3.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bicarbonate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	30.00	4.00	NC	NC	30.00	4.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	30.00	4.00	NC	NC	30.00	4.00
Q1, Q3	NC, NC	NC, NC	30.00, 30.00	4.00, 4.00	NC, NC	NC, NC	30.00, 30.00	4.00, 4.00
Min, Max	NC, NC	NC, NC	30.0, 30.0	4.0, 4.0	NC, NC	NC, NC	30.0, 30.0	4.0, 4.0
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	29.00	3.00	NC	NC	29.00	3.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	29.00	3.00	NC	NC	29.00	3.00
Q1, Q3	NC, NC	NC, NC	29.00, 29.00	3.00, 3.00	NC, NC	NC, NC	29.00, 29.00	3.00, 3.00
Min, Max	NC, NC	NC, NC	29.0, 29.0	3.0, 3.0	NC, NC	NC, NC	29.0, 29.0	3.0, 3.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bicarbonate (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	26.00	0.33	27.00	0.00	27.91	0.19	27.29	0.17
SD	1.000	2.082	2.160	2.160	3.010	3.642	2.505	2.875
Median	26.00	1.00	27.50	-0.50	26.50	0.50	27.00	0.00
Q1, Q3	25.00, 27.00	-2.00, 2.00	25.50, 28.50	-1.50, 1.50	25.50, 31.00	-2.50, 3.00	25.00, 29.00	-2.00, 3.00
Min, Max	25.0, 27.0	-2.0, 2.0	24.0, 29.0	-2.0, 3.0	25.0, 32.3	-5.2, 4.7	24.0, 32.3	-5.2, 4.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urate (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Baseline								
Nx	4		7		10		21	
Mean	336.1		320.6		346.6		335.9	
SD	121.46		72.34		123.76		103.99	
Median	309.3		339.0		368.8		339.0	
Q1, Q3	255.8, 416.4		237.9, 392.6		257.0, 404.5		257.0, 400.0	
Min, Max	220, 506		220, 400		172, 571		172, 571	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	343.0	-7.9	310.5	2.0	353.9	7.4	338.5	3.2
SD	156.28	55.27	59.62	34.41	116.21	42.41	104.16	39.98
Median	255.8	17.8	309.3	-3.0	350.9	3.0	333.1	0.0
Q1, Q3	249.8, 523.4	-71.4, 29.7	255.8, 345.0	-17.8, 5.9	237.9, 452.0	-28.0, 47.6	249.8, 400.0	-28.0, 29.7
Min, Max	250, 523	-71, 30	244, 400	-36, 65	229, 565	-65, 65	229, 565	-71, 65

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urate (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	341.0	-9.9	792.1	443.8	317.3	-29.7	458.1	109.8
SD	136.20	20.89	1005.75	970.96	123.65	37.30	539.91	516.12
Median	297.4	-11.9	303.3	-29.7	273.6	-23.8	285.5	-26.8
Q1, Q3	232.0, 493.7	-29.7, 11.9	267.7, 1316.5	-47.6, 935.1	199.0, 404.5	-53.5, 0.0	237.9, 404.5	-47.6, 0.0
Min, Max	232, 494	-30, 12	262, 2300	-65, 1900	196, 523	-89, 24	196, 2300	-89, 1900
Cycle 2 Day 1								
Nx	0	0	4	4	8	8	12	12
Mean	NC	NC	328.9	-19.5	329.9	-23.8	329.5	-22.3
SD	NC	NC	48.48	39.74	135.46	63.22	110.98	54.58
Median	NC	NC	318.7	-23.8	311.1	-23.8	312.3	-23.8
Q1, Q3	NC, NC	NC, NC	291.5, 366.3	-50.8, 11.9	211.2, 443.1	-33.8, 22.0	264.7, 416.4	-38.7, 17.8
Min, Max	NC, NC	NC, NC	286, 393	-60, 30	167, 541	-161, 42	167, 541	-161, 42

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urate (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	309.3	89.2	343.9	-4.5	334.6	1.0	335.7	7.0
SD	NC	NC	56.16	17.76	96.58	72.80	75.54	59.12
Median	309.3	89.2	348.0	-5.9	318.2	-5.8	315.2	0.0
Q1, Q3	309.3, 309.3	89.2, 89.2	297.4, 390.3	-17.8, 8.9	267.7, 410.4	-47.6, 65.4	267.7, 400.0	-35.7, 65.4
Min, Max	309, 309	89, 89	280, 400	-24, 18	223, 470	-95, 95	223, 470	-95, 95
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	261.7	41.6	357.3	9.0	317.8	-9.9	328.0	2.8
SD	NC	NC	53.32	15.85	97.20	45.92	77.94	35.99
Median	261.7	41.6	348.0	5.9	333.1	-5.9	336.1	5.9
Q1, Q3	261.7, 261.7	41.6, 41.6	321.2, 393.4	-3.0, 20.9	220.1, 398.5	-35.7, 16.0	261.7, 398.5	-5.9, 30.0
Min, Max	262, 262	42, 42	303, 430	-6, 30	215, 422	-71, 48	215, 430	-71, 48

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urate (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	363.7	15.4	310.4	-17.3	334.1	-2.7
SD	NC	NC	39.65	24.15	123.16	19.08	94.68	26.41
Median	NC	NC	350.9	10.0	356.9	-9.0	356.9	-5.9
Q1, Q3	NC, NC	NC, NC	336.1, 391.4	-3.0, 33.8	190.0, 380.7	-23.8, -5.9	333.1, 380.7	-9.0, 0.0
Min, Max	NC, NC	NC, NC	333, 420	-6, 48	172, 452	-48, 0	172, 452	-48, 48
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	337.1	5.9	333.1	-11.9	335.1	-3.0
SD	NC	NC	49.88	17.84	140.63	11.90	94.40	16.72
Median	NC	NC	362.8	5.9	392.6	-11.9	365.8	-5.9
Q1, Q3	NC, NC	NC, NC	279.6, 368.8	-11.9, 23.8	172.5, 434.2	-23.8, 0.0	279.6, 392.6	-11.9, 5.9
Min, Max	NC, NC	NC, NC	280, 369	-12, 24	172, 434	-24, 0	172, 434	-24, 24

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urate (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	309.3	-21.8	395.5	-35.7	343.8	-27.4
SD	NC	NC	50.82	19.12	37.85	0.00	62.30	15.51
Median	NC	NC	303.3	-29.7	395.5	-35.7	362.8	-35.7
Q1, Q3	NC, NC	NC, NC	261.7, 362.8	-35.7, 0.0	368.8, 422.3	-35.7, -35.7	303.3, 368.8	-35.7, -29.7
Min, Max	NC, NC	NC, NC	262, 363	-36, 0	369, 422	-36, -36	262, 422	-36, 0
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	374.7	11.9	386.6	-44.6	382.7	-25.8
SD	NC	NC	NC	NC	33.65	4.21	24.76	32.76
Median	NC	NC	374.7	11.9	386.6	-44.6	374.7	-41.6
Q1, Q3	NC, NC	NC, NC	374.7, 374.7	11.9, 11.9	362.8, 410.4	-47.6, -41.6	362.8, 410.4	-47.6, 11.9
Min, Max	NC, NC	NC, NC	375, 375	12, 12	363, 410	-48, -42	363, 410	-48, 12

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urate (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	386.6	23.8	440.2	-17.8	413.4	3.0
SD	NC	NC	NC	NC	NC	NC	37.85	29.44
Median	NC	NC	386.6	23.8	440.2	-17.8	413.4	3.0
Q1, Q3	NC, NC	NC, NC	386.6, 386.6	23.8, 23.8	440.2, 440.2	-17.8, -17.8	386.6, 440.2	-17.8, 23.8
Min, Max	NC, NC	NC, NC	387, 387	24, 24	440, 440	-18, -18	387, 440	-18, 24
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	368.8	5.9	428.3	-29.7	398.5	-11.9
SD	NC	NC	NC	NC	NC	NC	42.06	25.24
Median	NC	NC	368.8	5.9	428.3	-29.7	398.5	-11.9
Q1, Q3	NC, NC	NC, NC	368.8, 368.8	5.9, 5.9	428.3, 428.3	-29.7, -29.7	368.8, 428.3	-29.7, 5.9
Min, Max	NC, NC	NC, NC	369, 369	6, 6	428, 428	-30, -30	369, 428	-30, 6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urate (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	297.4	-65.4	446.1	-11.9	371.8	-38.7
SD	NC	NC	NC	NC	NC	NC	105.15	37.85
Median	NC	NC	297.4	-65.4	446.1	-11.9	371.8	-38.7
Q1, Q3	NC, NC	NC, NC	297.4, 297.4	-65.4, -65.4	446.1, 446.1	-11.9, -11.9	297.4, 446.1	-65.4, -11.9
Min, Max	NC, NC	NC, NC	297, 297	-65, -65	446, 446	-12, -12	297, 446	-65, -12
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	362.8	0.0	NC	NC	362.8	0.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	362.8	0.0	NC	NC	362.8	0.0
Q1, Q3	NC, NC	NC, NC	362.8, 362.8	0.0, 0.0	NC, NC	NC, NC	362.8, 362.8	0.0, 0.0
Min, Max	NC, NC	NC, NC	363, 363	0, 0	NC, NC	NC, NC	363, 363	0, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urate (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	398.5	35.7	NC	NC	398.5	35.7
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	398.5	35.7	NC	NC	398.5	35.7
Q1, Q3	NC, NC	NC, NC	398.5, 398.5	35.7, 35.7	NC, NC	NC, NC	398.5, 398.5	35.7, 35.7
Min, Max	NC, NC	NC, NC	399, 399	36, 36	NC, NC	NC, NC	399, 399	36, 36
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	392.6	29.7	NC	NC	392.6	29.7
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	392.6	29.7	NC	NC	392.6	29.7
Q1, Q3	NC, NC	NC, NC	392.6, 392.6	29.7, 29.7	NC, NC	NC, NC	392.6, 392.6	29.7, 29.7
Min, Max	NC, NC	NC, NC	393, 393	30, 30	NC, NC	NC, NC	393, 393	30, 30

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Urate (umol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	273.6	-77.3	346.3	-2.0	316.1	-24.9	315.6	-29.3
SD	48.69	111.12	43.36	14.09	140.44	20.34	106.07	52.26
Median	261.7	-95.2	359.9	-0.0	291.5	-17.8	327.1	-11.9
Q1, Q3	232.0, 327.1	-178.4, 41.6	315.2, 377.4	-13.0, 8.9	208.5, 410.4	-28.9, -11.9	246.0, 374.7	-29.7, -5.9
Min, Max	232, 327	-178, 42	286, 380	-20, 12	149, 559	-71, -11	149, 559	-178, 42

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Potassium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	4.23		4.37		14.65		9.24	
SD	0.499		0.377		32.453		22.405	
Median	4.10		4.50		4.40		4.30	
Q1, Q3	3.85, 4.60		4.00, 4.70		4.00, 5.10		4.00, 4.70	
Min, Max	3.8, 4.9		3.8, 4.8		3.6, 107.0		3.6, 107.0	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	4.10	-0.27	4.07	-0.25	4.27	-10.38	4.18	-5.58
SD	0.361	0.208	0.350	0.532	0.356	32.440	0.349	23.521
Median	4.20	-0.20	4.00	-0.30	4.30	-0.25	4.20	-0.20
Q1, Q3	3.70, 4.40	-0.50, -0.10	3.90, 4.30	-0.60, 0.10	4.00, 4.40	-0.40, 0.00	3.90, 4.40	-0.60, 0.00
Min, Max	3.7, 4.4	-0.5, -0.1	3.6, 4.6	-0.9, 0.5	3.8, 5.0	-102.7, 0.6	3.6, 5.0	-102.7, 0.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Potassium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	4.20	-0.17	3.95	-0.33	4.19	-14.74	4.12	-7.50
SD	0.520	0.764	0.451	0.320	0.248	38.654	0.360	27.317
Median	3.90	0.00	3.80	-0.35	4.20	-0.20	4.00	-0.15
Q1, Q3	3.90, 4.80	-1.00, 0.50	3.65, 4.25	-0.60, -0.05	4.00, 4.40	-0.50, 0.00	3.90, 4.40	-0.60, 0.00
Min, Max	3.9, 4.8	-1.0, 0.5	3.6, 4.6	-0.6, 0.0	3.9, 4.6	-102.4, 0.2	3.6, 4.8	-102.4, 0.5
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	4.40	-0.20	4.20	-0.08	4.40	-12.96	4.34	-7.46
SD	0.424	0.000	0.735	0.457	0.389	36.180	0.478	27.357
Median	4.40	-0.20	4.05	-0.10	4.40	-0.15	4.40	-0.20
Q1, Q3	4.10, 4.70	-0.20, -0.20	3.60, 4.80	-0.40, 0.25	4.10, 4.60	-0.55, 0.00	4.00, 4.70	-0.30, 0.00
Min, Max	4.1, 4.7	-0.2, -0.2	3.6, 5.1	-0.6, 0.5	3.9, 5.1	-102.5, 0.2	3.6, 5.1	-102.5, 0.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Potassium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	5.40	0.50	3.98	-0.30	4.45	-17.12	4.36	-9.40
SD	NC	NC	0.492	0.271	0.362	41.780	0.557	30.846
Median	5.40	0.50	4.00	-0.20	4.50	-0.10	4.40	-0.20
Q1, Q3	5.40, 5.40	0.50, 0.50	3.55, 4.40	-0.45, -0.15	4.20, 4.70	-0.20, 0.00	3.90, 4.70	-0.20, 0.00
Min, Max	5.4, 5.4	0.5, 0.5	3.5, 4.4	-0.7, -0.1	3.9, 4.9	-102.4, 0.1	3.5, 5.4	-102.4, 0.5
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	4.80	-0.10	4.18	-0.10	4.60	-20.44	4.45	-10.27
SD	NC	NC	0.624	0.455	0.430	45.817	0.521	32.373
Median	4.80	-0.10	3.90	-0.20	4.60	0.00	4.60	-0.05
Q1, Q3	4.80, 4.80	-0.10, -0.10	3.80, 4.55	-0.45, 0.25	4.60, 4.90	-0.20, 0.10	3.90, 4.90	-0.40, 0.10
Min, Max	4.8, 4.8	-0.1, -0.1	3.8, 5.1	-0.5, 0.5	3.9, 5.0	-102.4, 0.3	3.8, 5.1	-102.4, 0.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Potassium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	4.40	0.13	4.60	-20.44	4.51	-11.30
SD	NC	NC	0.622	0.403	0.212	45.933	0.423	34.241
Median	NC	NC	4.20	-0.00	4.60	-0.30	4.40	-0.10
Q1, Q3	NC, NC	NC, NC	4.00, 4.80	-0.15, 0.40	4.40, 4.70	-0.50, 0.10	4.30, 4.70	-0.30, 0.10
Min, Max	NC, NC	NC, NC	3.9, 5.3	-0.2, 0.7	4.4, 4.9	-102.6, 1.1	3.9, 5.3	-102.6, 1.1
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	4.10	-0.20	4.53	-34.40	4.32	-17.30
SD	NC	NC	0.700	0.265	0.252	58.976	0.527	41.740
Median	NC	NC	4.40	-0.10	4.50	-0.40	4.45	-0.35
Q1, Q3	NC, NC	NC, NC	3.30, 4.60	-0.50, 0.00	4.30, 4.80	-102.50, -0.30	4.30, 4.60	-0.50, -0.10
Min, Max	NC, NC	NC, NC	3.3, 4.6	-0.5, 0.0	4.3, 4.8	-102.5, -0.3	3.3, 4.8	-102.5, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Potassium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	4.57	0.27	4.45	-51.60	4.52	-20.48
SD	NC	NC	1.387	1.069	0.071	72.125	0.983	45.914
Median	NC	NC	4.20	-0.30	4.45	-51.60	4.40	-0.40
Q1, Q3	NC, NC	NC, NC	3.40, 6.10	-0.40, 1.50	4.40, 4.50	-102.60, -0.60	4.20, 4.50	-0.60, -0.30
Min, Max	NC, NC	NC, NC	3.4, 6.1	-0.4, 1.5	4.4, 4.5	-102.6, -0.6	3.4, 6.1	-102.6, 1.5
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	4.10	-0.40	4.55	-51.50	4.40	-34.47
SD	NC	NC	NC	NC	0.495	72.549	0.436	59.178
Median	NC	NC	4.10	-0.40	4.55	-51.50	4.20	-0.40
Q1, Q3	NC, NC	NC, NC	4.10, 4.10	-0.40, -0.40	4.20, 4.90	-102.80, -0.20	4.10, 4.90	-102.80, -0.20
Min, Max	NC, NC	NC, NC	4.1, 4.1	-0.4, -0.4	4.2, 4.9	-102.8, -0.2	4.1, 4.9	-102.8, -0.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Potassium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	4.60	0.10	4.40	-102.60	4.50	-51.25
SD	NC	NC	NC	NC	NC	NC	0.141	72.620
Median	NC	NC	4.60	0.10	4.40	-102.60	4.50	-51.25
Q1, Q3	NC, NC	NC, NC	4.60, 4.60	0.10, 0.10	4.40, 4.40	-102.60, - 102.60	4.40, 4.60	-102.60, 0.10
Min, Max	NC, NC	NC, NC	4.6, 4.6	0.1, 0.1	4.4, 4.4	-102.6, -102.6	4.4, 4.6	-102.6, 0.1
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	4.50	0.00	4.40	-102.60	4.45	-51.30
SD	NC	NC	NC	NC	NC	NC	0.071	72.549
Median	NC	NC	4.50	0.00	4.40	-102.60	4.45	-51.30
Q1, Q3	NC, NC	NC, NC	4.50, 4.50	0.00, 0.00	4.40, 4.40	-102.60, - 102.60	4.40, 4.50	-102.60, 0.00
Min, Max	NC, NC	NC, NC	4.5, 4.5	0.0, 0.0	4.4, 4.4	-102.6, -102.6	4.4, 4.5	-102.6, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Potassium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	4.20	-0.30	4.40	-102.60	4.30	-51.45
SD	NC	NC	NC	NC	NC	NC	0.141	72.337
Median	NC	NC	4.20	-0.30	4.40	-102.60	4.30	-51.45
Q1, Q3	NC, NC	NC, NC	4.20, 4.20	-0.30, -0.30	4.40, 4.40	-102.60, - 102.60	4.20, 4.40	-102.60, -0.30
Min, Max	NC, NC	NC, NC	4.2, 4.2	-0.3, -0.3	4.4, 4.4	-102.6, -102.6	4.2, 4.4	-102.6, -0.3
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.30	-0.20	NC	NC	4.30	-0.20
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.30	-0.20	NC	NC	4.30	-0.20
Q1, Q3	NC, NC	NC, NC	4.30, 4.30	-0.20, -0.20	NC, NC	NC, NC	4.30, 4.30	-0.20, -0.20
Min, Max	NC, NC	NC, NC	4.3, 4.3	-0.2, -0.2	NC, NC	NC, NC	4.3, 4.3	-0.2, -0.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Potassium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.30	-0.20	NC	NC	4.30	-0.20
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.30	-0.20	NC	NC	4.30	-0.20
Q1, Q3	NC, NC	NC, NC	4.30, 4.30	-0.20, -0.20	NC, NC	NC, NC	4.30, 4.30	-0.20, -0.20
Min, Max	NC, NC	NC, NC	4.3, 4.3	-0.2, -0.2	NC, NC	NC, NC	4.3, 4.3	-0.2, -0.2
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.40	-0.10	NC	NC	4.40	-0.10
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.40	-0.10	NC	NC	4.40	-0.10
Q1, Q3	NC, NC	NC, NC	4.40, 4.40	-0.10, -0.10	NC, NC	NC, NC	4.40, 4.40	-0.10, -0.10
Min, Max	NC, NC	NC, NC	4.4, 4.4	-0.1, -0.1	NC, NC	NC, NC	4.4, 4.4	-0.1, -0.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Potassium (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	7	7	14	14
Mean	4.37	0.00	4.20	-0.08	4.44	-14.61	4.36	-7.33
SD	0.666	0.361	0.935	0.759	0.382	38.801	0.591	27.426
Median	4.70	-0.10	3.75	-0.30	4.50	0.10	4.45	-0.10
Q1, Q3	3.60, 4.80	-0.30, 0.40	3.70, 4.70	-0.60, 0.45	4.30, 4.70	-0.60, 0.30	3.70, 4.70	-0.50, 0.30
Min, Max	3.6, 4.8	-0.3, 0.4	3.7, 5.6	-0.7, 1.0	3.7, 4.9	-102.6, 0.8	3.6, 5.6	-102.6, 1.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Sodium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	137.5		138.0		138.3		138.0	
SD	1.29		4.40		2.91		3.15	
Median	137.5		140.0		137.5		138.0	
Q1, Q3	136.5, 138.5		135.0, 142.0		137.0, 141.0		136.0, 140.0	
Min, Max	136, 139		131, 143		133, 142		131, 143	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	134.7	-3.3	137.2	-1.3	138.7	0.4	137.6	-0.7
SD	3.21	2.52	4.45	1.03	3.06	1.96	3.67	2.21
Median	136.0	-3.0	138.5	-1.0	138.5	0.0	137.0	-1.0
Q1, Q3	131.0, 137.0	-6.0, -1.0	134.0, 141.0	-2.0, -1.0	137.0, 142.0	0.0, 2.0	136.0, 141.0	-2.0, 0.0
Min, Max	131, 137	-6, -1	130, 141	-3, 0	133, 142	-3, 3	130, 142	-6, 3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Sodium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	134.7	-3.3	140.5	-0.8	138.7	0.0	138.4	-0.9
SD	1.53	0.58	1.00	0.96	2.93	1.29	3.03	1.69
Median	135.0	-3.0	140.0	-0.5	139.0	0.0	139.5	-0.5
Q1, Q3	133.0, 136.0	-4.0, -3.0	140.0, 141.0	-1.5, 0.0	136.0, 141.0	-1.0, 1.0	136.0, 141.0	-2.0, 0.0
Min, Max	133, 136	-4, -3	140, 142	-2, 0	134, 142	-2, 2	133, 142	-4, 2
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	137.0	-1.5	140.8	-0.5	137.9	-0.1	138.6	-0.4
SD	2.83	3.54	0.96	1.00	2.70	1.46	2.62	1.60
Median	137.0	-1.5	140.5	0.0	136.5	-0.5	139.5	0.0
Q1, Q3	135.0, 139.0	-4.0, 1.0	140.0, 141.5	-1.0, 0.0	136.0, 140.5	-1.0, 1.0	136.0, 141.0	-1.0, 0.0
Min, Max	135, 139	-4, 1	140, 142	-2, 0	135, 142	-2, 2	135, 142	-4, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Sodium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	139.0	0.0	140.5	-0.8	138.7	-0.5	139.4	-0.5
SD	NC	NC	1.29	0.50	2.73	1.87	2.25	1.37
Median	139.0	0.0	140.5	-1.0	138.0	-0.5	139.0	-1.0
Q1, Q3	139.0, 139.0	0.0, 0.0	139.5, 141.5	-1.0, -0.5	136.0, 142.0	-2.0, 1.0	138.0, 142.0	-1.0, 0.0
Min, Max	139, 139	0, 0	139, 142	-1, 0	136, 142	-3, 2	136, 142	-3, 2
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	135.0	-4.0	139.8	-1.5	139.2	-0.4	139.0	-1.2
SD	NC	NC	0.96	1.00	2.28	1.52	2.16	1.62
Median	135.0	-4.0	139.5	-1.0	140.0	-1.0	139.5	-1.0
Q1, Q3	135.0, 135.0	-4.0, -4.0	139.0, 140.5	-2.0, -1.0	138.0, 140.0	-1.0, 0.0	138.0, 140.0	-2.0, -1.0
Min, Max	135, 135	-4, -4	139, 141	-3, -1	136, 142	-2, 2	135, 142	-4, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Sodium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	140.8	-0.5	140.2	0.6	140.4	0.1
SD	NC	NC	1.71	1.29	2.59	1.14	2.13	1.27
Median	NC	NC	140.5	-0.5	139.0	1.0	140.0	0.0
Q1, Q3	NC, NC	NC, NC	139.5, 142.0	-1.5, 0.5	138.0, 143.0	0.0, 1.0	139.0, 143.0	-1.0, 1.0
Min, Max	NC, NC	NC, NC	139, 143	-2, 1	138, 143	-1, 2	138, 143	-2, 2
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	140.3	-0.3	139.3	0.0	139.8	-0.2
SD	NC	NC	1.15	1.15	2.52	2.00	1.83	1.47
Median	NC	NC	141.0	-1.0	139.0	0.0	140.0	-0.5
Q1, Q3	NC, NC	NC, NC	139.0, 141.0	-1.0, 1.0	137.0, 142.0	-2.0, 2.0	139.0, 141.0	-1.0, 1.0
Min, Max	NC, NC	NC, NC	139, 141	-1, 1	137, 142	-2, 2	137, 142	-2, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Sodium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	141.7	1.0	138.5	0.0	140.4	0.6
SD	NC	NC	3.79	2.65	0.71	1.41	3.21	2.07
Median	NC	NC	140.0	0.0	138.5	0.0	139.0	0.0
Q1, Q3	NC, NC	NC, NC	139.0, 146.0	-1.0, 4.0	138.0, 139.0	-1.0, 1.0	139.0, 140.0	-1.0, 1.0
Min, Max	NC, NC	NC, NC	139, 146	-1, 4	138, 139	-1, 1	138, 146	-1, 4
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	139.0	-1.0	137.5	-1.0	138.0	-1.0
SD	NC	NC	NC	NC	3.54	1.41	2.65	1.00
Median	NC	NC	139.0	-1.0	137.5	-1.0	139.0	-1.0
Q1, Q3	NC, NC	NC, NC	139.0, 139.0	-1.0, -1.0	135.0, 140.0	-2.0, 0.0	135.0, 140.0	-2.0, 0.0
Min, Max	NC, NC	NC, NC	139, 139	-1, -1	135, 140	-2, 0	135, 140	-2, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Sodium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	140.0	0.0	140.0	0.0	140.0	0.0
SD	NC	NC	NC	NC	NC	NC	0.00	0.00
Median	NC	NC	140.0	0.0	140.0	0.0	140.0	0.0
Q1, Q3	NC, NC	NC, NC	140.0, 140.0	0.0, 0.0	140.0, 140.0	0.0, 0.0	140.0, 140.0	0.0, 0.0
Min, Max	NC, NC	NC, NC	140, 140	0, 0	140, 140	0, 0	140, 140	0, 0
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	140.0	0.0	139.0	-1.0	139.5	-0.5
SD	NC	NC	NC	NC	NC	NC	0.71	0.71
Median	NC	NC	140.0	0.0	139.0	-1.0	139.5	-0.5
Q1, Q3	NC, NC	NC, NC	140.0, 140.0	0.0, 0.0	139.0, 139.0	-1.0, -1.0	139.0, 140.0	-1.0, 0.0
Min, Max	NC, NC	NC, NC	140, 140	0, 0	139, 139	-1, -1	139, 140	-1, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Sodium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	139.0	-1.0	139.0	-1.0	139.0	-1.0
SD	NC	NC	NC	NC	NC	NC	0.00	0.00
Median	NC	NC	139.0	-1.0	139.0	-1.0	139.0	-1.0
Q1, Q3	NC, NC	NC, NC	139.0, 139.0	-1.0, -1.0	139.0, 139.0	-1.0, -1.0	139.0, 139.0	-1.0, -1.0
Min, Max	NC, NC	NC, NC	139, 139	-1, -1	139, 139	-1, -1	139, 139	-1, -1
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	141.0	1.0	NC	NC	141.0	1.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	141.0	1.0	NC	NC	141.0	1.0
Q1, Q3	NC, NC	NC, NC	141.0, 141.0	1.0, 1.0	NC, NC	NC, NC	141.0, 141.0	1.0, 1.0
Min, Max	NC, NC	NC, NC	141, 141	1, 1	NC, NC	NC, NC	141, 141	1, 1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Sodium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	142.0	2.0	NC	NC	142.0	2.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	142.0	2.0	NC	NC	142.0	2.0
Q1, Q3	NC, NC	NC, NC	142.0, 142.0	2.0, 2.0	NC, NC	NC, NC	142.0, 142.0	2.0, 2.0
Min, Max	NC, NC	NC, NC	142, 142	2, 2	NC, NC	NC, NC	142, 142	2, 2
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	140.0	0.0	NC	NC	140.0	0.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	140.0	0.0	NC	NC	140.0	0.0
Q1, Q3	NC, NC	NC, NC	140.0, 140.0	0.0, 0.0	NC, NC	NC, NC	140.0, 140.0	0.0, 0.0
Min, Max	NC, NC	NC, NC	140, 140	0, 0	NC, NC	NC, NC	140, 140	0, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Sodium (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	135.3	-2.7	139.3	-2.0	137.0	-1.0	137.3	-1.6
SD	0.58	1.15	2.22	2.16	2.78	2.14	2.63	1.99
Median	135.0	-2.0	140.0	-2.5	138.0	-1.5	138.0	-2.0
Q1, Q3	135.0, 136.0	-4.0, -2.0	138.0, 140.5	-3.5, -0.5	135.0, 139.0	-2.5, 1.0	135.0, 140.0	-3.0, 1.0
Min, Max	135, 136	-4, -2	136, 141	-4, 1	132, 140	-4, 2	132, 141	-4, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Calcium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	2.369		2.408		2.366		2.380	
SD	0.0554		0.3613		0.1574		0.2262	
Median	2.375		2.280		2.380		2.360	
Q1, Q3	2.325, 2.413		2.125, 2.600		2.320, 2.450		2.280, 2.425	
Min, Max	2.30, 2.43		2.08, 3.13		2.10, 2.68		2.08, 3.13	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	2.358	0.000	2.334	-0.121	2.363	-0.003	2.353	-0.040
SD	0.0629	0.1090	0.2697	0.1785	0.2048	0.1505	0.2044	0.1571
Median	2.350	0.050	2.403	-0.125	2.335	0.000	2.350	0.000
Q1, Q3	2.300, 2.425	-0.125, 0.075	2.050, 2.425	-0.200, 0.025	2.225, 2.450	-0.025, 0.050	2.225, 2.425	-0.125, 0.050
Min, Max	2.30, 2.43	-0.13, 0.08	2.00, 2.73	-0.40, 0.10	2.03, 2.68	-0.33, 0.28	2.00, 2.73	-0.40, 0.28

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Calcium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	2.300	-0.058	2.325	-0.014	2.337	-0.044	2.326	-0.039
SD	0.1090	0.1258	0.2189	0.0962	0.1311	0.1163	0.1451	0.1054
Median	2.250	-0.075	2.388	-0.015	2.300	-0.075	2.300	-0.068
Q1, Q3	2.225, 2.425	-0.175, 0.075	2.163, 2.488	-0.088, 0.060	2.250, 2.450	-0.100, 0.100	2.250, 2.450	-0.100, 0.075
Min, Max	2.23, 2.43	-0.18, 0.08	2.03, 2.50	-0.13, 0.10	2.20, 2.58	-0.20, 0.13	2.03, 2.58	-0.20, 0.13
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	2.425	0.100	2.348	0.009	2.306	-0.116	2.335	-0.050
SD	0.0354	0.0000	0.2138	0.1071	0.0803	0.0979	0.1262	0.1226
Median	2.425	0.100	2.370	-0.008	2.288	-0.115	2.338	-0.058
Q1, Q3	2.400, 2.450	0.100, 0.100	2.170, 2.525	-0.070, 0.088	2.245, 2.375	-0.200, -0.038	2.240, 2.425	-0.120, 0.025
Min, Max	2.40, 2.45	0.10, 0.10	2.10, 2.55	-0.10, 0.15	2.21, 2.43	-0.25, 0.03	2.10, 2.55	-0.25, 0.15

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Calcium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	2.425	0.125	2.414	0.075	2.413	0.023	2.415	0.051
SD	NC	NC	0.2358	0.0890	0.0983	0.1065	0.1467	0.0965
Median	2.425	0.125	2.440	0.050	2.450	0.050	2.450	0.075
Q1, Q3	2.425, 2.425	0.125, 0.125	2.215, 2.613	0.013, 0.138	2.300, 2.500	-0.040, 0.100	2.280, 2.500	0.000, 0.125
Min, Max	2.43, 2.43	0.13, 0.13	2.15, 2.63	0.00, 0.20	2.28, 2.50	-0.15, 0.13	2.15, 2.63	-0.15, 0.20
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	2.300	0.000	2.389	0.050	2.513	0.134	2.442	0.087
SD	NC	NC	0.1898	0.0707	0.1384	0.0976	0.1638	0.0926
Median	2.300	0.000	2.440	0.075	2.500	0.125	2.488	0.088
Q1, Q3	2.300, 2.300	0.000, 0.000	2.253, 2.525	-0.000, 0.100	2.475, 2.525	0.075, 0.175	2.340, 2.525	0.020, 0.125
Min, Max	2.30, 2.30	0.00, 0.00	2.13, 2.55	-0.05, 0.10	2.34, 2.73	0.02, 0.28	2.13, 2.73	-0.05, 0.28

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Calcium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	2.363	0.024	2.387	0.008	2.376	0.015
SD	NC	NC	0.1762	0.1069	0.0910	0.0803	0.1263	0.0870
Median	NC	NC	2.375	0.035	2.425	0.025	2.425	0.025
Q1, Q3	NC, NC	NC, NC	2.213, 2.513	-0.065, 0.113	2.325, 2.450	-0.060, 0.025	2.260, 2.475	-0.060, 0.100
Min, Max	NC, NC	NC, NC	2.18, 2.53	-0.10, 0.13	2.26, 2.48	-0.08, 0.13	2.18, 2.53	-0.10, 0.13
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	2.442	0.083	2.367	-0.025	2.404	0.029
SD	NC	NC	0.1528	0.1127	0.1010	0.0433	0.1229	0.0967
Median	NC	NC	2.475	0.075	2.350	-0.050	2.413	0.000
Q1, Q3	NC, NC	NC, NC	2.275, 2.575	-0.025, 0.200	2.275, 2.475	-0.050, 0.025	2.275, 2.475	-0.050, 0.075
Min, Max	NC, NC	NC, NC	2.28, 2.58	-0.03, 0.20	2.28, 2.48	-0.05, 0.03	2.28, 2.58	-0.05, 0.20

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Calcium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	2.442	0.083	2.388	0.000	2.420	0.050
SD	NC	NC	0.1627	0.1041	0.0884	0.0000	0.1267	0.0866
Median	NC	NC	2.450	0.050	2.388	0.000	2.450	0.000
Q1, Q3	NC, NC	NC, NC	2.275, 2.600	0.000, 0.200	2.325, 2.450	0.000, 0.000	2.325, 2.450	0.000, 0.050
Min, Max	NC, NC	NC, NC	2.28, 2.60	0.00, 0.20	2.33, 2.45	0.00, 0.00	2.28, 2.60	0.00, 0.20
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	2.525	-0.075	2.413	0.025	2.450	-0.008
SD	NC	NC	NC	NC	0.0177	0.0707	0.0661	0.0764
Median	NC	NC	2.525	-0.075	2.413	0.025	2.425	-0.025
Q1, Q3	NC, NC	NC, NC	2.525, 2.525	-0.075, -0.075	2.400, 2.425	-0.025, 0.075	2.400, 2.525	-0.075, 0.075
Min, Max	NC, NC	NC, NC	2.53, 2.53	-0.08, -0.08	2.40, 2.43	-0.03, 0.08	2.40, 2.53	-0.08, 0.08

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Calcium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	2.500	-0.100	2.350	0.025	2.425	-0.038
SD	NC	NC	NC	NC	NC	NC	0.1061	0.0884
Median	NC	NC	2.500	-0.100	2.350	0.025	2.425	-0.038
Q1, Q3	NC, NC	NC, NC	2.500, 2.500	-0.100, -0.100	2.350, 2.350	0.025, 0.025	2.350, 2.500	-0.100, 0.025
Min, Max	NC, NC	NC, NC	2.50, 2.50	-0.10, -0.10	2.35, 2.35	0.03, 0.03	2.35, 2.50	-0.10, 0.03
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	2.675	0.075	2.275	-0.050	2.475	0.013
SD	NC	NC	NC	NC	NC	NC	0.2828	0.0884
Median	NC	NC	2.675	0.075	2.275	-0.050	2.475	0.013
Q1, Q3	NC, NC	NC, NC	2.675, 2.675	0.075, 0.075	2.275, 2.275	-0.050, -0.050	2.275, 2.675	-0.050, 0.075
Min, Max	NC, NC	NC, NC	2.68, 2.68	0.08, 0.08	2.28, 2.28	-0.05, -0.05	2.28, 2.68	-0.05, 0.08

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Calcium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	2.675	0.075	2.300	-0.025	2.488	0.025
SD	NC	NC	NC	NC	NC	NC	0.2652	0.0707
Median	NC	NC	2.675	0.075	2.300	-0.025	2.488	0.025
Q1, Q3	NC, NC	NC, NC	2.675, 2.675	0.075, 0.075	2.300, 2.300	-0.025, -0.025	2.300, 2.675	-0.025, 0.075
Min, Max	NC, NC	NC, NC	2.68, 2.68	0.08, 0.08	2.30, 2.30	-0.03, -0.03	2.30, 2.68	-0.03, 0.08
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	2.675	0.075	NC	NC	2.675	0.075
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	2.675	0.075	NC	NC	2.675	0.075
Q1, Q3	NC, NC	NC, NC	2.675, 2.675	0.075, 0.075	NC, NC	NC, NC	2.675, 2.675	0.075, 0.075
Min, Max	NC, NC	NC, NC	2.68, 2.68	0.08, 0.08	NC, NC	NC, NC	2.68, 2.68	0.08, 0.08

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Calcium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	2.650	0.050	NC	NC	2.650	0.050
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	2.650	0.050	NC	NC	2.650	0.050
Q1, Q3	NC, NC	NC, NC	2.650, 2.650	0.050, 0.050	NC, NC	NC, NC	2.650, 2.650	0.050, 0.050
Min, Max	NC, NC	NC, NC	2.65, 2.65	0.05, 0.05	NC, NC	NC, NC	2.65, 2.65	0.05, 0.05
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	2.675	0.075	NC	NC	2.675	0.075
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	2.675	0.075	NC	NC	2.675	0.075
Q1, Q3	NC, NC	NC, NC	2.675, 2.675	0.075, 0.075	NC, NC	NC, NC	2.675, 2.675	0.075, 0.075
Min, Max	NC, NC	NC, NC	2.68, 2.68	0.08, 0.08	NC, NC	NC, NC	2.68, 2.68	0.08, 0.08

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Calcium (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	2.242	-0.117	2.374	0.035	2.310	-0.069	2.313	-0.051
SD	0.0520	0.1127	0.0936	0.1363	0.1067	0.1177	0.1005	0.1262
Median	2.225	-0.125	2.360	0.020	2.300	-0.078	2.300	-0.075
Q1, Q3	2.200, 2.300	-0.225, 0.000	2.313, 2.435	-0.075, 0.145	2.258, 2.363	-0.138, -0.038	2.240, 2.370	-0.125, 0.000
Min, Max	2.20, 2.30	-0.23, 0.00	2.28, 2.50	-0.10, 0.20	2.14, 2.50	-0.22, 0.18	2.14, 2.50	-0.23, 0.20

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Chloride (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	102.0		101.6		101.8		101.8	
SD	4.08		4.54		3.12		3.62	
Median	102.0		101.0		102.0		102.0	
Q1, Q3	99.5, 104.5		101.0, 104.0		100.0, 103.0		101.0, 103.0	
Min, Max	97, 107		93, 108		95, 107		93, 108	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	102.3	-1.3	102.3	0.7	102.4	0.6	102.4	0.3
SD	5.77	2.89	5.54	1.51	2.46	2.50	3.90	2.29
Median	99.0	-3.0	103.0	0.0	102.5	0.5	102.0	0.0
Q1, Q3	99.0, 109.0	-3.0, 2.0	101.0, 104.0	0.0, 2.0	102.0, 104.0	-1.0, 1.0	99.0, 104.0	-1.0, 1.0
Min, Max	99, 109	-3, 2	93, 110	-1, 3	98, 106	-2, 7	93, 110	-3, 7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Chloride (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	101.0	-2.7	103.5	-0.5	102.7	0.3	102.6	-0.6
SD	2.65	0.58	3.11	1.29	3.68	2.63	3.23	2.24
Median	100.0	-3.0	102.5	-0.5	105.0	-1.0	102.5	-1.5
Q1, Q3	99.0, 104.0	-3.0, -2.0	101.5, 105.5	-1.5, 0.5	98.0, 105.0	-2.0, 3.0	100.0, 105.0	-2.0, 1.0
Min, Max	99, 104	-3, -2	101, 108	-2, 1	98, 107	-2, 4	98, 108	-3, 4
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	102.0	-2.5	103.8	-0.3	102.8	1.1	102.9	0.2
SD	4.24	0.71	4.27	2.06	3.15	1.73	3.36	2.08
Median	102.0	-2.5	102.0	0.0	103.5	0.5	102.5	0.0
Q1, Q3	99.0, 105.0	-3.0, -2.0	101.0, 106.5	-1.5, 1.0	99.5, 105.0	0.0, 2.5	100.0, 105.0	-1.0, 2.0
Min, Max	99, 105	-3, -2	101, 110	-3, 2	99, 107	-1, 4	99, 110	-3, 4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Chloride (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	101.0	-1.0	104.3	0.3	102.3	-0.7	102.9	-0.4
SD	NC	NC	3.20	1.71	1.97	1.51	2.51	1.50
Median	101.0	-1.0	103.0	0.5	103.0	0.0	103.0	0.0
Q1, Q3	101.0, 101.0	-1.0, -1.0	102.5, 106.0	-1.0, 1.5	100.0, 104.0	-2.0, 0.0	101.0, 104.0	-2.0, 1.0
Min, Max	101, 101	-1, -1	102, 109	-2, 2	100, 104	-3, 1	100, 109	-3, 2
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	97.0	-5.0	104.3	0.3	102.2	-1.0	102.5	-0.9
SD	NC	NC	3.40	0.50	2.59	2.45	3.41	2.28
Median	97.0	-5.0	103.5	0.0	103.0	-2.0	103.0	0.0
Q1, Q3	97.0, 97.0	-5.0, -5.0	102.0, 106.5	0.0, 0.5	102.0, 103.0	-2.0, 1.0	101.0, 104.0	-2.0, 1.0
Min, Max	97, 97	-5, -5	101, 109	0, 1	98, 105	-4, 2	97, 109	-5, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Chloride (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	105.3	1.3	104.0	0.8	104.6	1.0
SD	NC	NC	2.22	0.96	3.74	2.77	3.05	2.06
Median	NC	NC	105.0	1.5	104.0	0.0	104.0	1.0
Q1, Q3	NC, NC	NC, NC	103.5, 107.0	0.5, 2.0	104.0, 106.0	-1.0, 2.0	104.0, 106.0	0.0, 2.0
Min, Max	NC, NC	NC, NC	103, 108	0, 2	98, 108	-2, 5	98, 108	-2, 5
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	103.7	-0.3	104.0	-0.7	103.8	-0.5
SD	NC	NC	2.08	1.53	1.73	0.58	1.72	1.05
Median	NC	NC	103.0	0.0	103.0	-1.0	103.0	-0.5
Q1, Q3	NC, NC	NC, NC	102.0, 106.0	-2.0, 1.0	103.0, 106.0	-1.0, 0.0	103.0, 106.0	-1.0, 0.0
Min, Max	NC, NC	NC, NC	102, 106	-2, 1	103, 106	-1, 0	102, 106	-2, 1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Chloride (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	104.3	0.3	104.5	-1.0	104.4	-0.2
SD	NC	NC	4.04	1.15	0.71	2.83	2.88	1.79
Median	NC	NC	102.0	1.0	104.5	-1.0	104.0	1.0
Q1, Q3	NC, NC	NC, NC	102.0, 109.0	-1.0, 1.0	104.0, 105.0	-3.0, 1.0	102.0, 105.0	-1.0, 1.0
Min, Max	NC, NC	NC, NC	102, 109	-1, 1	104, 105	-3, 1	102, 109	-3, 1
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	103.0	0.0	104.0	-1.5	103.7	-1.0
SD	NC	NC	NC	NC	2.83	0.71	2.08	1.00
Median	NC	NC	103.0	0.0	104.0	-1.5	103.0	-1.0
Q1, Q3	NC, NC	NC, NC	103.0, 103.0	0.0, 0.0	102.0, 106.0	-2.0, -1.0	102.0, 106.0	-2.0, 0.0
Min, Max	NC, NC	NC, NC	103, 103	0, 0	102, 106	-2, -1	102, 106	-2, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Chloride (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	103.0	0.0	104.0	-3.0	103.5	-1.5
SD	NC	NC	NC	NC	NC	NC	0.71	2.12
Median	NC	NC	103.0	0.0	104.0	-3.0	103.5	-1.5
Q1, Q3	NC, NC	NC, NC	103.0, 103.0	0.0, 0.0	104.0, 104.0	-3.0, -3.0	103.0, 104.0	-3.0, 0.0
Min, Max	NC, NC	NC, NC	103, 103	0, 0	104, 104	-3, -3	103, 104	-3, 0
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	103.0	0.0	104.0	-3.0	103.5	-1.5
SD	NC	NC	NC	NC	NC	NC	0.71	2.12
Median	NC	NC	103.0	0.0	104.0	-3.0	103.5	-1.5
Q1, Q3	NC, NC	NC, NC	103.0, 103.0	0.0, 0.0	104.0, 104.0	-3.0, -3.0	103.0, 104.0	-3.0, 0.0
Min, Max	NC, NC	NC, NC	103, 103	0, 0	104, 104	-3, -3	103, 104	-3, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Chloride (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	99.0	-4.0	106.0	-1.0	102.5	-2.5
SD	NC	NC	NC	NC	NC	NC	4.95	2.12
Median	NC	NC	99.0	-4.0	106.0	-1.0	102.5	-2.5
Q1, Q3	NC, NC	NC, NC	99.0, 99.0	-4.0, -4.0	106.0, 106.0	-1.0, -1.0	99.0, 106.0	-4.0, -1.0
Min, Max	NC, NC	NC, NC	99, 99	-4, -4	106, 106	-1, -1	99, 106	-4, -1
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	105.0	2.0	NC	NC	105.0	2.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	105.0	2.0	NC	NC	105.0	2.0
Q1, Q3	NC, NC	NC, NC	105.0, 105.0	2.0, 2.0	NC, NC	NC, NC	105.0, 105.0	2.0, 2.0
Min, Max	NC, NC	NC, NC	105, 105	2, 2	NC, NC	NC, NC	105, 105	2, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Chloride (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	103.0	0.0	NC	NC	103.0	0.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	103.0	0.0	NC	NC	103.0	0.0
Q1, Q3	NC, NC	NC, NC	103.0, 103.0	0.0, 0.0	NC, NC	NC, NC	103.0, 103.0	0.0, 0.0
Min, Max	NC, NC	NC, NC	103, 103	0, 0	NC, NC	NC, NC	103, 103	0, 0
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	104.0	1.0	NC	NC	104.0	1.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	104.0	1.0	NC	NC	104.0	1.0
Q1, Q3	NC, NC	NC, NC	104.0, 104.0	1.0, 1.0	NC, NC	NC, NC	104.0, 104.0	1.0, 1.0
Min, Max	NC, NC	NC, NC	104, 104	1, 1	NC, NC	NC, NC	104, 104	1, 1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Chloride (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	100.0	-3.7	102.3	-1.8	101.4	-0.4	101.3	-1.4
SD	4.36	1.53	5.06	2.75	4.17	2.92	4.19	2.82
Median	98.0	-4.0	102.5	-1.5	102.0	-0.5	102.0	-1.0
Q1, Q3	97.0, 105.0	-5.0, -2.0	98.5, 106.0	-4.0, 0.5	98.0, 104.5	-2.0, 1.5	97.0, 105.0	-4.0, 0.0
Min, Max	97, 105	-5, -2	96, 108	-5, 1	95, 107	-5, 4	95, 108	-5, 4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Magnesium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	1.800		1.473		1.291		1.449	
SD	0.4000		0.6554		0.6106		0.5983	
Median	2.000		1.200		1.050		1.200	
Q1, Q3	1.600, 2.000		0.860, 2.200		0.800, 2.100		0.860, 2.000	
Min, Max	1.20, 2.00		0.80, 2.40		0.74, 2.20		0.74, 2.40	
Cycle 1 Day 6								
Nx	2	2	6	6	10	10	18	18
Mean	1.475	-0.125	1.377	-0.042	1.304	0.013	1.347	-0.021
SD	0.4596	0.1061	0.6933	0.1201	0.6052	0.0706	0.5925	0.0982
Median	1.475	-0.125	1.050	0.000	1.025	0.010	1.125	0.000
Q1, Q3	1.150, 1.800	-0.200, -0.050	0.860, 2.100	-0.100, 0.000	0.800, 2.000	0.000, 0.060	0.840, 2.000	-0.100, 0.050
Min, Max	1.15, 1.80	-0.20, -0.05	0.80, 2.40	-0.25, 0.10	0.75, 2.20	-0.10, 0.10	0.75, 2.40	-0.25, 0.10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Magnesium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	1.667	-0.067	1.163	-0.065	1.363	-0.007	1.371	-0.036
SD	0.4163	0.1155	0.5089	0.1589	0.6634	0.0886	0.5685	0.1115
Median	1.800	0.000	0.975	-0.005	0.950	0.000	1.150	0.000
Q1, Q3	1.200, 2.000	-0.200, 0.000	0.825, 1.500	-0.155, 0.025	0.750, 2.100	-0.100, 0.050	0.850, 2.000	-0.100, 0.000
Min, Max	1.20, 2.00	-0.20, 0.00	0.80, 1.90	-0.30, 0.05	0.74, 2.10	-0.10, 0.15	0.74, 2.10	-0.30, 0.15
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	1.525	-0.075	1.250	0.023	1.194	0.005	1.257	-0.001
SD	0.5303	0.0354	0.6390	0.0519	0.6309	0.1093	0.5863	0.0905
Median	1.525	-0.075	0.975	0.000	0.900	0.000	0.975	0.000
Q1, Q3	1.150, 1.900	-0.100, -0.050	0.875, 1.625	-0.005, 0.050	0.775, 1.575	-0.065, 0.060	0.850, 1.900	-0.050, 0.020
Min, Max	1.15, 1.90	-0.10, -0.05	0.85, 2.20	-0.01, 0.10	0.75, 2.30	-0.15, 0.20	0.75, 2.30	-0.15, 0.20

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Magnesium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	1.150	-0.050	1.153	-0.075	1.335	0.037	1.252	-0.012
SD	NC	NC	0.4484	0.2255	0.6368	0.1178	0.5217	0.1592
Median	1.150	-0.050	1.000	0.000	1.000	0.035	1.050	0.000
Q1, Q3	1.150, 1.150	-0.050, -0.050	0.855, 1.450	-0.225, 0.075	0.900, 2.100	0.000, 0.100	0.900, 1.800	-0.050, 0.100
Min, Max	1.15, 1.15	-0.05, -0.05	0.81, 1.80	-0.40, 0.10	0.81, 2.20	-0.15, 0.20	0.81, 2.20	-0.40, 0.20
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	1.350	0.150	1.303	0.075	1.450	0.042	1.381	0.066
SD	NC	NC	0.6723	0.0645	0.7929	0.1076	0.6600	0.0876
Median	1.350	0.150	1.025	0.075	1.150	0.010	1.125	0.075
Q1, Q3	1.350, 1.350	0.150, 0.150	0.905, 1.700	0.025, 0.125	0.750, 2.300	-0.050, 0.100	0.860, 2.300	0.000, 0.150
Min, Max	1.35, 1.35	0.15, 0.15	0.86, 2.30	0.00, 0.15	0.75, 2.30	-0.05, 0.20	0.75, 2.30	-0.05, 0.20

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Magnesium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	1.235	0.008	1.368	-0.040	1.309	-0.019
SD	NC	NC	0.5176	0.1480	0.6857	0.1140	0.5835	0.1238
Median	NC	NC	1.025	0.040	1.100	0.000	1.100	0.000
Q1, Q3	NC, NC	NC, NC	0.920, 1.550	-0.085, 0.100	0.800, 2.000	-0.100, 0.000	0.890, 2.000	-0.100, 0.050
Min, Max	NC, NC	NC, NC	0.89, 2.00	-0.20, 0.15	0.74, 2.20	-0.20, 0.10	0.74, 2.20	-0.20, 0.15
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	1.283	-0.067	1.300	-0.100	1.292	-0.083
SD	NC	NC	0.5485	0.2021	0.7089	0.0500	0.5669	0.1329
Median	NC	NC	1.100	0.050	1.050	-0.100	1.075	-0.075
Q1, Q3	NC, NC	NC, NC	0.850, 1.900	-0.300, 0.050	0.750, 2.100	-0.150, -0.050	0.850, 1.900	-0.150, 0.050
Min, Max	NC, NC	NC, NC	0.85, 1.90	-0.30, 0.05	0.75, 2.10	-0.15, -0.05	0.75, 2.10	-0.30, 0.05

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Magnesium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	1.383	0.033	0.925	-0.075	1.200	-0.010
SD	NC	NC	0.7974	0.0764	0.1768	0.1061	0.6235	0.0962
Median	NC	NC	1.000	0.050	0.925	-0.075	1.000	0.000
Q1, Q3	NC, NC	NC, NC	0.850, 2.300	-0.050, 0.100	0.800, 1.050	-0.150, 0.000	0.850, 1.050	-0.050, 0.050
Min, Max	NC, NC	NC, NC	0.85, 2.30	-0.05, 0.10	0.80, 1.05	-0.15, 0.00	0.80, 2.30	-0.15, 0.10
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	0.850	0.050	0.925	-0.075	0.900	-0.033
SD	NC	NC	NC	NC	0.3182	0.0354	0.2291	0.0764
Median	NC	NC	0.850	0.050	0.925	-0.075	0.850	-0.050
Q1, Q3	NC, NC	NC, NC	0.850, 0.850	0.050, 0.050	0.700, 1.150	-0.100, -0.050	0.700, 1.150	-0.100, 0.050
Min, Max	NC, NC	NC, NC	0.85, 0.85	0.05, 0.05	0.70, 1.15	-0.10, -0.05	0.70, 1.15	-0.10, 0.05

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Magnesium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.950	0.150	0.700	-0.100	0.825	0.025
SD	NC	NC	NC	NC	NC	NC	0.1768	0.1768
Median	NC	NC	0.950	0.150	0.700	-0.100	0.825	0.025
Q1, Q3	NC, NC	NC, NC	0.950, 0.950	0.150, 0.150	0.700, 0.700	-0.100, -0.100	0.700, 0.950	-0.100, 0.150
Min, Max	NC, NC	NC, NC	0.95, 0.95	0.15, 0.15	0.70, 0.70	-0.10, -0.10	0.70, 0.95	-0.10, 0.15
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.900	0.100	0.700	-0.100	0.800	-0.000
SD	NC	NC	NC	NC	NC	NC	0.1414	0.1414
Median	NC	NC	0.900	0.100	0.700	-0.100	0.800	-0.000
Q1, Q3	NC, NC	NC, NC	0.900, 0.900	0.100, 0.100	0.700, 0.700	-0.100, -0.100	0.700, 0.900	-0.100, 0.100
Min, Max	NC, NC	NC, NC	0.90, 0.90	0.10, 0.10	0.70, 0.70	-0.10, -0.10	0.70, 0.90	-0.10, 0.10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Magnesium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.900	0.100	0.700	-0.100	0.800	-0.000
SD	NC	NC	NC	NC	NC	NC	0.1414	0.1414
Median	NC	NC	0.900	0.100	0.700	-0.100	0.800	-0.000
Q1, Q3	NC, NC	NC, NC	0.900, 0.900	0.100, 0.100	0.700, 0.700	-0.100, -0.100	0.700, 0.900	-0.100, 0.100
Min, Max	NC, NC	NC, NC	0.90, 0.90	0.10, 0.10	0.70, 0.70	-0.10, -0.10	0.70, 0.90	-0.10, 0.10
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.850	0.050	NC	NC	0.850	0.050
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.850	0.050	NC	NC	0.850	0.050
Q1, Q3	NC, NC	NC, NC	0.850, 0.850	0.050, 0.050	NC, NC	NC, NC	0.850, 0.850	0.050, 0.050
Min, Max	NC, NC	NC, NC	0.85, 0.85	0.05, 0.05	NC, NC	NC, NC	0.85, 0.85	0.05, 0.05

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Magnesium (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.850	0.050	NC	NC	0.850	0.050
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.850	0.050	NC	NC	0.850	0.050
Q1, Q3	NC, NC	NC, NC	0.850, 0.850	0.050, 0.050	NC, NC	NC, NC	0.850, 0.850	0.050, 0.050
Min, Max	NC, NC	NC, NC	0.85, 0.85	0.05, 0.05	NC, NC	NC, NC	0.85, 0.85	0.05, 0.05
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.900	0.100	NC	NC	0.900	0.100
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.900	0.100	NC	NC	0.900	0.100
Q1, Q3	NC, NC	NC, NC	0.900, 0.900	0.100, 0.100	NC, NC	NC, NC	0.900, 0.900	0.100, 0.100
Min, Max	NC, NC	NC, NC	0.90, 0.90	0.10, 0.10	NC, NC	NC, NC	0.90, 0.90	0.10, 0.10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Magnesium (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	1.717	-0.017	3.255	2.028	1.301	-0.056	1.905	0.507
SD	0.3175	0.1443	3.8787	4.1151	0.7054	0.1175	2.0551	2.1305
Median	1.900	-0.100	1.600	-0.020	0.975	-0.015	1.350	-0.030
Q1, Q3	1.350, 1.900	-0.100, 0.150	0.910, 5.600	-0.045, 4.100	0.770, 2.100	-0.125, 0.005	0.820, 2.100	-0.100, 0.010
Min, Max	1.35, 1.90	-0.10, 0.15	0.82, 9.00	-0.05, 8.20	0.52, 2.20	-0.28, 0.10	0.52, 9.00	-0.28, 8.20

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Phosphate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	1.146		1.053		1.262		1.170	
SD	0.1194		0.1251		0.2329		0.2010	
Median	1.130		1.033		1.259		1.130	
Q1, Q3	1.049, 1.243		0.936, 1.130		1.066, 1.421		1.033, 1.270	
Min, Max	1.03, 1.29		0.90, 1.27		0.94, 1.71		0.90, 1.71	
Cycle 1 Day 6								
Nx	2	2	6	6	10	10	18	18
Mean	1.275	0.097	0.975	-0.070	1.259	-0.003	1.166	-0.015
SD	0.0228	0.1370	0.1894	0.0918	0.3186	0.2553	0.2891	0.2018
Median	1.275	0.097	0.969	-0.065	1.249	0.000	1.227	0.000
Q1, Q3	1.259, 1.292	0.000, 0.194	0.807, 1.033	-0.097, 0.000	1.195, 1.518	-0.032, 0.194	1.001, 1.300	-0.097, 0.097
Min, Max	1.26, 1.29	0.00, 0.19	0.77, 1.30	-0.23, 0.03	0.50, 1.58	-0.63, 0.26	0.50, 1.58	-0.63, 0.26

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Phosphate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	1.302	0.172	1.173	0.121	1.278	-0.050	1.253	0.047
SD	0.1657	0.2508	0.3896	0.3630	0.2947	0.1230	0.2868	0.2395
Median	1.259	0.097	1.150	0.063	1.292	0.000	1.275	0.015
Q1, Q3	1.162, 1.485	-0.032, 0.452	0.872, 1.473	-0.114, 0.355	1.070, 1.518	-0.129, 0.040	1.070, 1.485	-0.032, 0.097
Min, Max	1.16, 1.49	-0.03, 0.45	0.74, 1.65	-0.26, 0.61	0.77, 1.68	-0.29, 0.06	0.74, 1.68	-0.29, 0.61
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	1.292	0.242	1.094	0.042	1.176	-0.103	1.169	-0.012
SD	0.0457	0.0685	0.2077	0.2048	0.2437	0.1405	0.2148	0.1914
Median	1.292	0.242	1.098	0.004	1.119	-0.161	1.167	-0.081
Q1, Q3	1.259, 1.324	0.194, 0.291	0.920, 1.269	-0.097, 0.181	1.018, 1.340	-0.194, -0.010	0.970, 1.310	-0.161, 0.129
Min, Max	1.26, 1.32	0.19, 0.29	0.87, 1.31	-0.16, 0.32	0.87, 1.58	-0.23, 0.13	0.87, 1.58	-0.23, 0.32

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Phosphate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	1.324	0.258	1.002	-0.050	1.174	-0.058	1.125	-0.027
SD	NC	NC	0.1529	0.0613	0.3154	0.2181	0.2612	0.1840
Median	1.324	0.258	0.936	-0.068	1.275	0.048	1.230	0.032
Q1, Q3	1.324, 1.324	0.258, 0.258	0.920, 1.083	-0.097, -0.004	1.100, 1.324	-0.097, 0.065	0.936, 1.324	-0.097, 0.065
Min, Max	1.32, 1.32	0.26, 0.26	0.90, 1.23	-0.10, 0.03	0.58, 1.49	-0.48, 0.07	0.58, 1.49	-0.48, 0.26
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	1.098	0.032	1.046	-0.006	1.298	0.032	1.177	0.017
SD	NC	NC	0.2809	0.1259	0.1735	0.1898	0.2368	0.1472
Median	1.098	0.032	0.985	-0.032	1.259	-0.097	1.161	-0.032
Q1, Q3	1.098, 1.098	0.032, 0.032	0.872, 1.220	-0.081, 0.069	1.162, 1.324	-0.097, 0.130	1.001, 1.324	-0.097, 0.130
Min, Max	1.10, 1.10	0.03, 0.03	0.77, 1.44	-0.13, 0.17	1.16, 1.58	-0.10, 0.32	0.77, 1.58	-0.13, 0.32

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Phosphate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	0.993	-0.060	1.285	0.020	1.155	-0.016
SD	NC	NC	0.2075	0.0552	0.1402	0.1779	0.2229	0.1367
Median	NC	NC	0.936	-0.081	1.292	0.097	1.160	0.020
Q1, Q3	NC, NC	NC, NC	0.872, 1.113	-0.097, -0.022	1.160, 1.388	0.032, 0.129	0.936, 1.292	-0.097, 0.097
Min, Max	NC, NC	NC, NC	0.81, 1.29	-0.10, 0.02	1.13, 1.45	-0.29, 0.13	0.81, 1.45	-0.29, 0.13
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	1.012	0.032	1.324	0.011	1.168	0.022
SD	NC	NC	0.1305	0.0854	0.0969	0.1836	0.1995	0.1286
Median	NC	NC	1.033	0.000	1.324	0.065	1.179	0.032
Q1, Q3	NC, NC	NC, NC	0.872, 1.130	-0.032, 0.129	1.227, 1.421	-0.194, 0.161	1.033, 1.324	-0.032, 0.129
Min, Max	NC, NC	NC, NC	0.87, 1.13	-0.03, 0.13	1.23, 1.42	-0.19, 0.16	0.87, 1.42	-0.19, 0.16

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Phosphate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	1.184	0.205	1.162	-0.097	1.175	0.084
SD	NC	NC	0.1526	0.2150	0.0913	0.0913	0.1178	0.2290
Median	NC	NC	1.130	0.097	1.162	-0.097	1.130	0.065
Q1, Q3	NC, NC	NC, NC	1.066, 1.356	0.065, 0.452	1.098, 1.227	-0.161, -0.032	1.098, 1.227	-0.032, 0.097
Min, Max	NC, NC	NC, NC	1.07, 1.36	0.06, 0.45	1.10, 1.23	-0.16, -0.03	1.07, 1.36	-0.16, 0.45
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	0.775	-0.129	1.243	-0.016	1.087	-0.054
SD	NC	NC	NC	NC	0.3882	0.3882	0.3852	0.2821
Median	NC	NC	0.775	-0.129	1.243	-0.016	0.969	-0.129
Q1, Q3	NC, NC	NC, NC	0.775, 0.775	-0.129, -0.129	0.969, 1.518	-0.291, 0.258	0.775, 1.518	-0.291, 0.258
Min, Max	NC, NC	NC, NC	0.77, 0.77	-0.13, -0.13	0.97, 1.52	-0.29, 0.26	0.77, 1.52	-0.29, 0.26

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Phosphate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.743	-0.161	1.227	-0.032	0.985	-0.097
SD	NC	NC	NC	NC	NC	NC	0.3425	0.0913
Median	NC	NC	0.743	-0.161	1.227	-0.032	0.985	-0.097
Q1, Q3	NC, NC	NC, NC	0.743, 0.743	-0.161, -0.161	1.227, 1.227	-0.032, -0.032	0.743, 1.227	-0.161, -0.032
Min, Max	NC, NC	NC, NC	0.74, 0.74	-0.16, -0.16	1.23, 1.23	-0.03, -0.03	0.74, 1.23	-0.16, -0.03
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.840	-0.065	1.098	-0.161	0.969	-0.113
SD	NC	NC	NC	NC	NC	NC	0.1827	0.0685
Median	NC	NC	0.840	-0.065	1.098	-0.161	0.969	-0.113
Q1, Q3	NC, NC	NC, NC	0.840, 0.840	-0.065, -0.065	1.098, 1.098	-0.161, -0.161	0.840, 1.098	-0.161, -0.065
Min, Max	NC, NC	NC, NC	0.84, 0.84	-0.06, -0.06	1.10, 1.10	-0.16, -0.16	0.84, 1.10	-0.16, -0.06

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Phosphate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	1.195	0.291	1.001	-0.258	1.098	0.016
SD	NC	NC	NC	NC	NC	NC	0.1370	0.3882
Median	NC	NC	1.195	0.291	1.001	-0.258	1.098	0.016
Q1, Q3	NC, NC	NC, NC	1.195, 1.195	0.291, 0.291	1.001, 1.001	-0.258, -0.258	1.001, 1.195	-0.258, 0.291
Min, Max	NC, NC	NC, NC	1.19, 1.19	0.29, 0.29	1.00, 1.00	-0.26, -0.26	1.00, 1.19	-0.26, 0.29
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.840	-0.065	NC	NC	0.840	-0.065
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.840	-0.065	NC	NC	0.840	-0.065
Q1, Q3	NC, NC	NC, NC	0.840, 0.840	-0.065, -0.065	NC, NC	NC, NC	0.840, 0.840	-0.065, -0.065
Min, Max	NC, NC	NC, NC	0.84, 0.84	-0.06, -0.06	NC, NC	NC, NC	0.84, 0.84	-0.06, -0.06

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Phosphate (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	1.130	0.226	NC	NC	1.130	0.226
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	1.130	0.226	NC	NC	1.130	0.226
Q1, Q3	NC, NC	NC, NC	1.130, 1.130	0.226, 0.226	NC, NC	NC, NC	1.130, 1.130	0.226, 0.226
Min, Max	NC, NC	NC, NC	1.13, 1.13	0.23, 0.23	NC, NC	NC, NC	1.13, 1.13	0.23, 0.23
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.678	-0.226	NC	NC	0.678	-0.226
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.678	-0.226	NC	NC	0.678	-0.226
Q1, Q3	NC, NC	NC, NC	0.678, 0.678	-0.226, -0.226	NC, NC	NC, NC	0.678, 0.678	-0.226, -0.226
Min, Max	NC, NC	NC, NC	0.68, 0.68	-0.23, -0.23	NC, NC	NC, NC	0.68, 0.68	-0.23, -0.23

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Phosphate (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	1.238	0.108	1.065	0.013	1.359	0.032	1.256	0.042
SD	0.1305	0.1892	0.2093	0.0741	0.3578	0.3072	0.3041	0.2339
Median	1.259	0.032	1.066	0.041	1.324	-0.032	1.259	0.032
Q1, Q3	1.098, 1.356	-0.032, 0.323	0.936, 1.193	-0.032, 0.057	1.085, 1.550	-0.186, 0.135	1.066, 1.388	-0.161, 0.129
Min, Max	1.10, 1.36	-0.03, 0.32	0.81, 1.32	-0.10, 0.06	0.92, 2.03	-0.26, 0.68	0.81, 2.03	-0.26, 0.68

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Aspartate Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	47.0		47.6		28.6		38.4	
SD	27.17		24.06		14.02		21.57	
Median	39.5		43.0		24.5		34.0	
Q1, Q3	26.0, 68.0		24.0, 74.0		20.0, 36.0		23.0, 51.0	
Min, Max	26, 83		18, 83		9, 59		9, 83	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	58.0	4.0	40.0	-8.3	25.9	-2.7	35.4	-3.4
SD	51.22	25.36	25.73	13.53	12.09	7.75	26.28	13.03
Median	39.0	-7.0	30.5	-5.0	22.0	-0.5	26.0	-2.0
Q1, Q3	19.0, 116.0	-14.0, 33.0	22.0, 57.0	-22.0, -2.0	19.0, 30.0	-6.0, 1.0	19.0, 39.0	-13.0, 1.0
Min, Max	19, 116	-14, 33	16, 84	-26, 10	10, 53	-15, 12	10, 116	-26, 33

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Aspartate Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	46.7	-7.3	23.8	-9.5	26.6	-2.6	30.1	-5.6
SD	29.50	1.53	5.62	14.39	11.01	5.71	16.72	8.57
Median	47.0	-7.0	23.0	-4.5	28.0	0.0	26.5	-6.0
Q1, Q3	17.0, 76.0	-9.0, -6.0	19.5, 28.0	-19.5, 0.5	19.0, 28.0	-8.0, 2.0	19.0, 31.0	-9.0, 1.0
Min, Max	17, 76	-9, -6	18, 31	-30, 1	13, 48	-11, 4	13, 76	-30, 4
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	58.0	3.5	26.3	-7.0	28.3	1.6	31.9	-0.6
SD	59.40	19.09	4.11	17.03	17.61	6.78	23.77	11.75
Median	58.0	3.5	26.5	-3.5	21.5	-0.5	25.0	-0.5
Q1, Q3	16.0, 100.0	-10.0, 17.0	23.5, 29.0	-19.5, 5.5	16.5, 38.5	-2.5, 3.0	17.0, 34.0	-4.0, 4.0
Min, Max	16, 100	-10, 17	21, 31	-30, 9	10, 63	-4, 17	10, 100	-30, 17

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Aspartate Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	17.0	-9.0	25.0	-8.3	21.2	-0.7	22.2	-4.2
SD	NC	NC	5.48	14.91	11.11	7.37	8.78	10.50
Median	17.0	-9.0	25.0	-4.0	19.0	-1.5	22.0	-2.0
Q1, Q3	17.0, 17.0	-9.0, -9.0	20.5, 29.5	-19.0, 2.5	14.0, 28.0	-6.0, 0.0	16.0, 28.0	-9.0, 1.0
Min, Max	17, 17	-9, -9	19, 31	-29, 4	8, 39	-8, 13	8, 39	-29, 13
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	27.0	1.0	29.8	-3.5	18.8	-3.0	24.0	-2.8
SD	NC	NC	4.19	12.37	8.47	4.18	8.27	7.79
Median	27.0	1.0	30.5	0.0	18.0	-2.0	26.5	-1.5
Q1, Q3	27.0, 27.0	1.0, 1.0	27.0, 32.5	-13.0, 6.0	17.0, 26.0	-3.0, -1.0	18.0, 30.0	-6.0, 1.0
Min, Max	27, 27	1, 1	24, 34	-20, 6	6, 27	-10, 1	6, 34	-20, 6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Aspartate Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	33.8	0.5	20.4	-1.4	26.3	-0.6
SD	NC	NC	15.04	7.72	7.77	4.98	12.83	5.98
Median	NC	NC	28.0	4.0	20.0	0.0	26.0	0.0
Q1, Q3	NC, NC	NC, NC	25.0, 42.5	-4.0, 5.0	18.0, 26.0	0.0, 0.0	20.0, 29.0	0.0, 3.0
Min, Max	NC, NC	NC, NC	23, 56	-11, 5	9, 29	-10, 3	9, 56	-11, 5
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	27.7	0.3	23.0	1.7	25.3	1.0
SD	NC	NC	8.08	5.03	8.89	5.51	8.02	4.77
Median	NC	NC	29.0	1.0	20.0	2.0	24.5	1.5
Q1, Q3	NC, NC	NC, NC	19.0, 35.0	-5.0, 5.0	16.0, 33.0	-4.0, 7.0	19.0, 33.0	-4.0, 5.0
Min, Max	NC, NC	NC, NC	19, 35	-5, 5	16, 33	-4, 7	16, 35	-5, 7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Aspartate Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	26.3	-1.0	19.5	0.5	23.6	-0.4
SD	NC	NC	6.35	8.19	2.12	3.54	5.94	6.11
Median	NC	NC	30.0	1.0	19.5	0.5	21.0	1.0
Q1, Q3	NC, NC	NC, NC	19.0, 30.0	-10.0, 6.0	18.0, 21.0	-2.0, 3.0	19.0, 30.0	-2.0, 3.0
Min, Max	NC, NC	NC, NC	19, 30	-10, 6	18, 21	-2, 3	18, 30	-10, 6
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	17.0	-1.0	21.5	2.5	20.0	1.3
SD	NC	NC	NC	NC	0.71	2.12	2.65	2.52
Median	NC	NC	17.0	-1.0	21.5	2.5	21.0	1.0
Q1, Q3	NC, NC	NC, NC	17.0, 17.0	-1.0, -1.0	21.0, 22.0	1.0, 4.0	17.0, 22.0	-1.0, 4.0
Min, Max	NC, NC	NC, NC	17, 17	-1, -1	21, 22	1, 4	17, 22	-1, 4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Aspartate Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	22.0	4.0	29.0	11.0	25.5	7.5
SD	NC	NC	NC	NC	NC	NC	4.95	4.95
Median	NC	NC	22.0	4.0	29.0	11.0	25.5	7.5
Q1, Q3	NC, NC	NC, NC	22.0, 22.0	4.0, 4.0	29.0, 29.0	11.0, 11.0	22.0, 29.0	4.0, 11.0
Min, Max	NC, NC	NC, NC	22, 22	4, 4	29, 29	11, 11	22, 29	4, 11
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	20.0	2.0	18.0	0.0	19.0	1.0
SD	NC	NC	NC	NC	NC	NC	1.41	1.41
Median	NC	NC	20.0	2.0	18.0	0.0	19.0	1.0
Q1, Q3	NC, NC	NC, NC	20.0, 20.0	2.0, 2.0	18.0, 18.0	0.0, 0.0	18.0, 20.0	0.0, 2.0
Min, Max	NC, NC	NC, NC	20, 20	2, 2	18, 18	0, 0	18, 20	0, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Aspartate Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	32.0	14.0	18.0	0.0	25.0	7.0
SD	NC	NC	NC	NC	NC	NC	9.90	9.90
Median	NC	NC	32.0	14.0	18.0	0.0	25.0	7.0
Q1, Q3	NC, NC	NC, NC	32.0, 32.0	14.0, 14.0	18.0, 18.0	0.0, 0.0	18.0, 32.0	0.0, 14.0
Min, Max	NC, NC	NC, NC	32, 32	14, 14	18, 18	0, 0	18, 32	0, 14
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	26.0	8.0	NC	NC	26.0	8.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	26.0	8.0	NC	NC	26.0	8.0
Q1, Q3	NC, NC	NC, NC	26.0, 26.0	8.0, 8.0	NC, NC	NC, NC	26.0, 26.0	8.0, 8.0
Min, Max	NC, NC	NC, NC	26, 26	8, 8	NC, NC	NC, NC	26, 26	8, 8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Aspartate Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	22.0	4.0	NC	NC	22.0	4.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	22.0	4.0	NC	NC	22.0	4.0
Q1, Q3	NC, NC	NC, NC	22.0, 22.0	4.0, 4.0	NC, NC	NC, NC	22.0, 22.0	4.0, 4.0
Min, Max	NC, NC	NC, NC	22, 22	4, 4	NC, NC	NC, NC	22, 22	4, 4
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	21.0	3.0	NC	NC	21.0	3.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	21.0	3.0	NC	NC	21.0	3.0
Q1, Q3	NC, NC	NC, NC	21.0, 21.0	3.0, 3.0	NC, NC	NC, NC	21.0, 21.0	3.0, 3.0
Min, Max	NC, NC	NC, NC	21, 21	3, 3	NC, NC	NC, NC	21, 21	3, 3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Aspartate Aminotransferase (U/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	7	7	14	14
Mean	65.3	11.3	29.3	-4.0	26.7	-2.1	35.7	0.2
SD	57.95	33.71	4.92	13.09	16.39	10.02	30.09	17.25
Median	37.0	1.0	31.0	-2.5	23.0	-5.0	29.0	-2.5
Q1, Q3	27.0, 132.0	-16.0, 49.0	26.5, 32.0	-14.5, 6.5	14.0, 44.0	-9.0, 0.0	22.0, 37.0	-9.0, 4.0
Min, Max	27, 132	-16, 49	22, 33	-20, 9	9, 54	-13, 18	9, 132	-20, 49

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alanine Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	20.0		27.7		18.2		21.7	
SD	9.90		22.06		4.44		13.74	
Median	19.0		20.0		18.0		18.0	
Q1, Q3	13.5, 26.5		14.0, 33.0		15.0, 22.0		15.0, 22.0	
Min, Max	9, 33		11, 75		12, 26		9, 75	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	24.3	0.7	24.3	-4.7	17.6	-0.6	20.8	-1.7
SD	16.29	8.14	20.45	4.97	4.88	3.41	13.02	4.96
Median	17.0	-3.0	18.0	-3.5	16.5	-1.5	17.0	-2.0
Q1, Q3	13.0, 43.0	-5.0, 10.0	13.0, 22.0	-10.0, -2.0	13.0, 22.0	-3.0, 0.0	13.0, 22.0	-4.0, 0.0
Min, Max	13, 43	-5, 10	10, 65	-11, 2	12, 26	-4, 8	10, 65	-11, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alanine Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	21.0	-2.7	22.8	-9.8	17.4	-0.3	19.7	-3.5
SD	14.80	6.66	10.14	20.40	5.65	2.36	8.84	11.10
Median	14.0	-6.0	21.5	-1.0	15.0	0.0	15.5	-0.5
Q1, Q3	11.0, 38.0	-7.0, 5.0	14.5, 31.0	-22.0, 2.5	14.0, 22.0	-2.0, 2.0	14.0, 26.0	-4.0, 2.0
Min, Max	11, 38	-7, 5	13, 35	-40, 3	10, 26	-4, 3	10, 38	-40, 5
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	30.5	5.0	26.0	-6.5	17.5	-0.3	21.8	-1.3
SD	28.99	18.38	9.49	28.10	7.19	4.62	11.90	15.32
Median	30.5	5.0	29.5	0.5	15.5	-2.0	18.0	-2.0
Q1, Q3	10.0, 51.0	-8.0, 18.0	20.5, 31.5	-25.5, 12.5	12.5, 21.0	-3.0, 3.5	12.0, 30.0	-5.0, 6.0
Min, Max	10, 51	-8, 18	12, 33	-46, 19	10, 32	-6, 7	10, 51	-46, 19

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alanine Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	10.0	-8.0	23.3	-9.3	18.8	0.2	19.6	-4.0
SD	NC	NC	10.24	24.45	8.30	6.85	8.99	15.03
Median	10.0	-8.0	22.5	-1.0	19.0	-1.5	16.0	-3.0
Q1, Q3	10.0, 10.0	-8.0, -8.0	14.5, 32.0	-24.0, 5.5	12.0, 22.0	-3.0, 6.0	12.0, 30.0	-8.0, 6.0
Min, Max	10, 10	-8, -8	14, 34	-45, 10	9, 32	-9, 10	9, 34	-45, 10
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	17.0	-1.0	27.5	-5.0	18.6	0.6	22.0	-1.8
SD	NC	NC	15.00	18.67	6.80	4.72	10.87	11.57
Median	17.0	-1.0	27.0	-0.5	19.0	1.0	18.5	0.0
Q1, Q3	17.0, 17.0	-1.0, -1.0	15.0, 40.0	-18.0, 8.0	17.0, 20.0	-1.0, 2.0	17.0, 28.0	-5.0, 4.0
Min, Max	17, 17	-1, -1	12, 44	-31, 12	9, 28	-6, 7	9, 44	-31, 12

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alanine Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	41.5	9.0	17.4	-0.6	28.1	3.7
SD	NC	NC	45.04	16.79	4.34	2.51	30.52	11.60
Median	NC	NC	23.5	4.5	15.0	-1.0	17.0	0.0
Q1, Q3	NC, NC	NC, NC	14.0, 69.0	-1.5, 19.5	15.0, 17.0	-1.0, 0.0	15.0, 25.0	-1.0, 3.0
Min, Max	NC, NC	NC, NC	11, 108	-6, 33	15, 25	-4, 3	11, 108	-6, 33
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	22.3	4.0	18.7	2.3	20.5	3.2
SD	NC	NC	11.85	7.00	5.86	7.64	8.60	6.62
Median	NC	NC	16.0	1.0	21.0	4.0	18.5	2.5
Q1, Q3	NC, NC	NC, NC	15.0, 36.0	-1.0, 12.0	12.0, 23.0	-6.0, 9.0	15.0, 23.0	-1.0, 9.0
Min, Max	NC, NC	NC, NC	15, 36	-1, 12	12, 23	-6, 9	12, 36	-6, 12

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alanine Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	21.3	3.0	17.0	-1.5	19.6	1.2
SD	NC	NC	9.45	5.57	7.07	6.36	7.92	5.63
Median	NC	NC	18.0	4.0	17.0	-1.5	18.0	3.0
Q1, Q3	NC, NC	NC, NC	14.0, 32.0	-3.0, 8.0	12.0, 22.0	-6.0, 3.0	14.0, 22.0	-3.0, 4.0
Min, Max	NC, NC	NC, NC	14, 32	-3, 8	12, 22	-6, 3	12, 32	-6, 8
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	15.0	1.0	18.0	-0.5	17.0	0.0
SD	NC	NC	NC	NC	2.83	2.12	2.65	1.73
Median	NC	NC	15.0	1.0	18.0	-0.5	16.0	1.0
Q1, Q3	NC, NC	NC, NC	15.0, 15.0	1.0, 1.0	16.0, 20.0	-2.0, 1.0	15.0, 20.0	-2.0, 1.0
Min, Max	NC, NC	NC, NC	15, 15	1, 1	16, 20	-2, 1	15, 20	-2, 1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alanine Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	15.0	1.0	30.0	11.0	22.5	6.0
SD	NC	NC	NC	NC	NC	NC	10.61	7.07
Median	NC	NC	15.0	1.0	30.0	11.0	22.5	6.0
Q1, Q3	NC, NC	NC, NC	15.0, 15.0	1.0, 1.0	30.0, 30.0	11.0, 11.0	15.0, 30.0	1.0, 11.0
Min, Max	NC, NC	NC, NC	15, 15	1, 1	30, 30	11, 11	15, 30	1, 11
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	14.0	0.0	17.0	-2.0	15.5	-1.0
SD	NC	NC	NC	NC	NC	NC	2.12	1.41
Median	NC	NC	14.0	0.0	17.0	-2.0	15.5	-1.0
Q1, Q3	NC, NC	NC, NC	14.0, 14.0	0.0, 0.0	17.0, 17.0	-2.0, -2.0	14.0, 17.0	-2.0, 0.0
Min, Max	NC, NC	NC, NC	14, 14	0, 0	17, 17	-2, -2	14, 17	-2, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alanine Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	48.0	34.0	18.0	-1.0	33.0	16.5
SD	NC	NC	NC	NC	NC	NC	21.21	24.75
Median	NC	NC	48.0	34.0	18.0	-1.0	33.0	16.5
Q1, Q3	NC, NC	NC, NC	48.0, 48.0	34.0, 34.0	18.0, 18.0	-1.0, -1.0	18.0, 48.0	-1.0, 34.0
Min, Max	NC, NC	NC, NC	48, 48	34, 34	18, 18	-1, -1	18, 48	-1, 34
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	38.0	24.0	NC	NC	38.0	24.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	38.0	24.0	NC	NC	38.0	24.0
Q1, Q3	NC, NC	NC, NC	38.0, 38.0	24.0, 24.0	NC, NC	NC, NC	38.0, 38.0	24.0, 24.0
Min, Max	NC, NC	NC, NC	38, 38	24, 24	NC, NC	NC, NC	38, 38	24, 24

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alanine Aminotransferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	35.0	21.0	NC	NC	35.0	21.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	35.0	21.0	NC	NC	35.0	21.0
Q1, Q3	NC, NC	NC, NC	35.0, 35.0	21.0, 21.0	NC, NC	NC, NC	35.0, 35.0	21.0, 21.0
Min, Max	NC, NC	NC, NC	35, 35	21, 21	NC, NC	NC, NC	35, 35	21, 21
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	18.0	4.0	NC	NC	18.0	4.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	18.0	4.0	NC	NC	18.0	4.0
Q1, Q3	NC, NC	NC, NC	18.0, 18.0	4.0, 4.0	NC, NC	NC, NC	18.0, 18.0	4.0, 4.0
Min, Max	NC, NC	NC, NC	18, 18	4, 4	NC, NC	NC, NC	18, 18	4, 4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alanine Aminotransferase (U/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	45.7	22.0	24.3	-8.3	14.9	-2.4	23.5	0.9
SD	53.15	45.13	10.56	27.26	6.24	6.05	24.39	24.37
Median	17.0	-1.0	22.0	0.5	16.5	-2.0	17.0	-1.0
Q1, Q3	13.0, 107.0	-7.0, 74.0	16.0, 32.5	-24.0, 7.5	9.5, 20.0	-6.0, 2.5	13.0, 22.0	-7.0, 4.0
Min, Max	13, 107	-7, 74	15, 38	-48, 14	5, 22	-13, 5	5, 107	-48, 74

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alkaline Phosphatase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	196.50		199.71		90.20		146.95	
SD	100.540		204.615		26.225		132.143	
Median	192.00		99.00		87.00		99.00	
Q1, Q3	121.50, 271.50		76.00, 389.00		74.00, 107.00		77.00, 138.00	
Min, Max	82.0, 320.0		65.0, 585.0		46.0, 138.0		46.0, 585.0	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	117.63	-117.03	119.17	-16.33	88.50	-1.70	102.78	-24.53
SD	106.121	172.606	89.430	37.023	22.727	11.710	63.014	74.147
Median	135.00	-26.00	83.50	-3.00	87.50	-1.50	85.00	-4.00
Q1, Q3	3.90, 214.00	-316.10, -9.00	79.00, 109.00	-15.00, 3.00	65.00, 101.00	-14.00, 1.00	65.00, 122.00	-15.00, 1.00
Min, Max	3.9, 214.0	-316.1, -9.0	61.0, 299.0	-90.0, 10.0	63.0, 123.0	-15.0, 19.0	3.9, 299.0	-316.1, 19.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alkaline Phosphatase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	221.67	-13.00	75.50	-11.50	89.14	-1.86	113.64	-7.00
SD	123.977	48.073	16.503	13.178	27.757	17.131	79.037	23.661
Median	176.00	-34.00	73.50	-6.50	86.00	-5.00	91.50	-6.50
Q1, Q3	127.00, 362.00	-47.00, 42.00	63.50, 87.50	-19.00, -4.00	61.00, 115.00	-8.00, 12.00	69.00, 127.00	-31.00, 8.00
Min, Max	127.0, 362.0	-47.0, 42.0	58.0, 97.0	-31.0, -2.0	54.0, 127.0	-32.0, 20.0	54.0, 362.0	-47.0, 42.0
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	238.00	-2.50	79.00	-8.00	90.00	-2.75	108.00	-4.21
SD	141.421	28.991	12.702	9.764	31.090	16.051	71.794	15.217
Median	238.00	-2.50	81.00	-5.00	81.00	-6.00	85.00	-6.00
Q1, Q3	138.00, 338.00	-23.00, 18.00	70.00, 88.00	-14.50, -1.50	66.50, 115.00	-10.00, -2.00	72.00, 126.00	-12.00, 0.00
Min, Max	138.0, 338.0	-23.0, 18.0	62.0, 92.0	-22.0, 0.0	54.0, 141.0	-20.0, 34.0	54.0, 338.0	-23.0, 34.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alkaline Phosphatase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	153.00	-8.00	73.25	-13.75	94.33	-5.00	92.00	-8.45
SD	NC	NC	10.689	16.520	26.493	19.494	30.020	17.037
Median	153.00	-8.00	72.00	-9.50	92.00	-9.50	86.00	-8.00
Q1, Q3	153.00, 153.00	-8.00, -8.00	64.50, 82.00	-25.00, -2.50	81.00, 115.00	-22.00, 10.00	66.00, 115.00	-22.00, 1.00
Min, Max	153.0, 153.0	-8.0, -8.0	63.0, 86.0	-37.0, 1.0	55.0, 131.0	-23.0, 24.0	55.0, 153.0	-37.0, 24.0
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	209.00	48.00	79.25	-7.75	97.20	-3.80	101.20	-0.20
SD	NC	NC	6.850	14.033	27.599	17.683	43.225	22.255
Median	209.00	48.00	77.00	-7.50	106.00	-9.00	85.50	-7.00
Q1, Q3	209.00, 209.00	48.00, 48.00	74.50, 84.00	-17.50, 2.00	82.00, 111.00	-16.00, 4.00	75.00, 111.00	-16.00, 9.00
Min, Max	209.0, 209.0	48.0, 48.0	74.0, 89.0	-25.0, 9.0	58.0, 129.0	-21.0, 23.0	58.0, 209.0	-25.0, 48.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alkaline Phosphatase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	95.25	8.25	101.40	0.40	98.67	3.89
SD	NC	NC	42.201	39.601	35.956	30.221	36.397	32.586
Median	NC	NC	81.00	6.50	104.00	14.00	97.00	13.00
Q1, Q3	NC, NC	NC, NC	70.00, 120.50	-19.00, 35.50	97.00, 124.00	-30.00, 21.00	78.00, 124.00	-30.00, 21.00
Min, Max	NC, NC	NC, NC	62.0, 157.0	-38.0, 58.0	44.0, 138.0	-34.0, 31.0	44.0, 157.0	-38.0, 58.0
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	55.87	-27.13	86.00	-2.00	70.93	-14.57
SD	NC	NC	45.205	59.129	46.701	30.000	44.297	44.136
Median	NC	NC	73.00	6.00	81.00	-2.00	77.00	2.00
Q1, Q3	NC, NC	NC, NC	4.60, 90.00	-95.40, 8.00	42.00, 135.00	-32.00, 28.00	42.00, 90.00	-32.00, 8.00
Min, Max	NC, NC	NC, NC	4.6, 90.0	-95.4, 8.0	42.0, 135.0	-32.0, 28.0	4.6, 135.0	-95.4, 28.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alkaline Phosphatase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	80.33	-2.67	76.50	-2.00	78.80	-2.40
SD	NC	NC	10.017	8.327	41.719	35.355	22.129	18.636
Median	NC	NC	84.00	0.00	76.50	-2.00	84.00	0.00
Q1, Q3	NC, NC	NC, NC	69.00, 88.00	-12.00, 4.00	47.00, 106.00	-27.00, 23.00	69.00, 88.00	-12.00, 4.00
Min, Max	NC, NC	NC, NC	69.0, 88.0	-12.0, 4.0	47.0, 106.0	-27.0, 23.0	47.0, 106.0	-27.0, 23.0
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	62.00	-3.00	67.50	-11.00	65.67	-8.33
SD	NC	NC	NC	NC	27.577	21.213	19.757	15.695
Median	NC	NC	62.00	-3.00	67.50	-11.00	62.00	-3.00
Q1, Q3	NC, NC	NC, NC	62.00, 62.00	-3.00, -3.00	48.00, 87.00	-26.00, 4.00	48.00, 87.00	-26.00, 4.00
Min, Max	NC, NC	NC, NC	62.0, 62.0	-3.0, -3.0	48.0, 87.0	-26.0, 4.0	48.0, 87.0	-26.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alkaline Phosphatase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	68.00	3.00	79.00	-4.00	73.50	-0.50
SD	NC	NC	NC	NC	NC	NC	7.778	4.950
Median	NC	NC	68.00	3.00	79.00	-4.00	73.50	-0.50
Q1, Q3	NC, NC	NC, NC	68.00, 68.00	3.00, 3.00	79.00, 79.00	-4.00, -4.00	68.00, 79.00	-4.00, 3.00
Min, Max	NC, NC	NC, NC	68.0, 68.0	3.0, 3.0	79.0, 79.0	-4.0, -4.0	68.0, 79.0	-4.0, 3.0
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	69.00	4.00	87.00	4.00	78.00	4.00
SD	NC	NC	NC	NC	NC	NC	12.728	0.000
Median	NC	NC	69.00	4.00	87.00	4.00	78.00	4.00
Q1, Q3	NC, NC	NC, NC	69.00, 69.00	4.00, 4.00	87.00, 87.00	4.00, 4.00	69.00, 87.00	4.00, 4.00
Min, Max	NC, NC	NC, NC	69.0, 69.0	4.0, 4.0	87.0, 87.0	4.0, 4.0	69.0, 87.0	4.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alkaline Phosphatase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	82.00	17.00	76.00	-7.00	79.00	5.00
SD	NC	NC	NC	NC	NC	NC	4.243	16.971
Median	NC	NC	82.00	17.00	76.00	-7.00	79.00	5.00
Q1, Q3	NC, NC	NC, NC	82.00, 82.00	17.00, 17.00	76.00, 76.00	-7.00, -7.00	76.00, 82.00	-7.00, 17.00
Min, Max	NC, NC	NC, NC	82.0, 82.0	17.0, 17.0	76.0, 76.0	-7.0, -7.0	76.0, 82.0	-7.0, 17.0
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	68.00	3.00	NC	NC	68.00	3.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	68.00	3.00	NC	NC	68.00	3.00
Q1, Q3	NC, NC	NC, NC	68.00, 68.00	3.00, 3.00	NC, NC	NC, NC	68.00, 68.00	3.00, 3.00
Min, Max	NC, NC	NC, NC	68.0, 68.0	3.0, 3.0	NC, NC	NC, NC	68.0, 68.0	3.0, 3.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alkaline Phosphatase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	67.00	2.00	NC	NC	67.00	2.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	67.00	2.00	NC	NC	67.00	2.00
Q1, Q3	NC, NC	NC, NC	67.00, 67.00	2.00, 2.00	NC, NC	NC, NC	67.00, 67.00	2.00, 2.00
Min, Max	NC, NC	NC, NC	67.0, 67.0	2.0, 2.0	NC, NC	NC, NC	67.0, 67.0	2.0, 2.0
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	69.00	4.00	NC	NC	69.00	4.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	69.00	4.00	NC	NC	69.00	4.00
Q1, Q3	NC, NC	NC, NC	69.00, 69.00	4.00, 4.00	NC, NC	NC, NC	69.00, 69.00	4.00, 4.00
Min, Max	NC, NC	NC, NC	69.0, 69.0	4.0, 4.0	NC, NC	NC, NC	69.0, 69.0	4.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Alkaline Phosphatase (U/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	219.00	-15.67	99.00	12.00	90.88	3.75	118.67	2.07
SD	19.975	63.011	23.537	8.042	45.889	35.099	62.751	35.975
Median	209.00	-17.00	102.50	10.50	72.50	-6.00	114.00	5.00
Q1, Q3	206.00, 242.00	-78.00, 48.00	80.00, 118.00	5.50, 18.50	63.50, 117.50	-16.00, 15.50	69.00, 182.00	-17.00, 17.00
Min, Max	206.0, 242.0	-78.0, 48.0	70.0, 121.0	5.0, 22.0	38.0, 182.0	-36.0, 79.0	38.0, 242.0	-78.0, 79.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lactate Dehydrogenase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		8		19	
Mean	233.8		282.3		316.9		286.6	
SD	55.27		187.29		273.88		205.93	
Median	222.0		207.0		215.0		212.0	
Q1, Q3	192.5, 275.0		195.0, 291.0		187.5, 302.0		195.0, 291.0	
Min, Max	183, 308		119, 687		150, 976		119, 976	
Cycle 1 Day 6								
Nx	2	2	6	6	9	7	17	15
Mean	262.0	-13.0	278.0	-2.8	269.9	-41.7	271.8	-22.3
SD	18.38	28.28	228.90	26.20	186.58	87.81	183.93	63.01
Median	262.0	-13.0	196.5	-11.5	206.0	-12.0	207.0	-12.0
Q1, Q3	249.0, 275.0	-33.0, 7.0	183.0, 252.0	-18.0, 0.0	191.0, 210.0	-45.0, 0.0	186.0, 252.0	-24.0, 0.0
Min, Max	249, 275	-33, 7	105, 735	-24, 48	134, 740	-236, 18	105, 740	-236, 48

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lactate Dehydrogenase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	6	14	13
Mean	236.0	-8.3	208.5	-11.3	304.0	-39.0	262.1	-23.4
SD	7.00	63.69	33.01	30.41	237.37	112.87	168.08	80.27
Median	239.0	-14.0	209.5	-18.0	184.0	-31.5	215.5	-24.0
Q1, Q3	228.0, 241.0	-69.0, 58.0	180.0, 237.0	-32.0, 9.5	168.0, 500.0	-75.0, -22.0	182.0, 239.0	-40.0, -12.0
Min, Max	228, 241	-69, 58	177, 238	-40, 31	128, 763	-213, 139	128, 763	-213, 139
Cycle 2 Day 1								
Nx	2	2	4	4	8	6	14	12
Mean	229.0	-16.5	198.8	-21.0	286.3	-30.2	253.1	-24.8
SD	14.14	102.53	23.77	33.42	240.72	46.68	181.72	47.79
Median	229.0	-16.5	202.5	-17.5	197.5	-24.5	202.0	-21.0
Q1, Q3	219.0, 239.0	-89.0, 56.0	180.5, 217.0	-45.5, 3.5	194.0, 262.5	-41.0, -13.0	193.0, 222.0	-52.5, 3.5
Min, Max	219, 239	-89, 56	168, 222	-64, 15	116, 866	-110, 32	116, 866	-110, 56

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lactate Dehydrogenase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	4	11	9
Mean	280.0	-28.0	217.5	-2.3	212.0	-13.5	220.2	-10.1
SD	NC	NC	36.97	52.08	82.58	17.14	64.97	34.70
Median	280.0	-28.0	217.0	-0.5	199.5	-10.5	206.0	-12.0
Q1, Q3	280.0, 280.0	-28.0, -28.0	192.5, 242.5	-43.0, 38.5	189.0, 206.0	-24.5, -2.5	189.0, 263.0	-28.0, 4.0
Min, Max	280, 280	-28, -28	173, 263	-64, 56	113, 365	-37, 4	113, 365	-64, 56
Cycle 5 Day 1								
Nx	1	1	4	4	5	3	10	8
Mean	601.0	293.0	219.0	-0.8	187.6	-9.3	241.5	32.8
SD	NC	NC	21.59	29.57	32.11	9.02	129.66	107.12
Median	601.0	293.0	226.0	6.5	194.0	-10.0	209.5	-3.5
Q1, Q3	601.0, 601.0	293.0, 293.0	204.5, 233.5	-23.5, 22.0	193.0, 208.0	-18.0, 0.0	193.0, 231.0	-14.0, 22.0
Min, Max	601, 601	293, 293	188, 236	-40, 24	132, 211	-18, 0	132, 601	-40, 293

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lactate Dehydrogenase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	3	9	7
Mean	NC	NC	225.8	6.0	188.0	-10.3	204.8	-1.0
SD	NC	NC	37.37	28.74	31.11	12.22	37.46	23.22
Median	NC	NC	233.5	1.0	191.0	-13.0	201.0	-13.0
Q1, Q3	NC, NC	NC, NC	197.5, 254.0	-17.5, 29.5	190.0, 201.0	-21.0, 3.0	190.0, 221.0	-19.0, 18.0
Min, Max	NC, NC	NC, NC	176, 260	-19, 41	137, 221	-21, 3	137, 260	-21, 41
Cycle 9 Day 1								
Nx	0	0	3	3	3	1	6	4
Mean	NC	NC	219.7	18.7	188.3	3.0	204.0	14.8
SD	NC	NC	30.07	24.58	24.17	NC	29.83	21.55
Median	NC	NC	207.0	6.0	185.0	3.0	202.5	4.5
Q1, Q3	NC, NC	NC, NC	198.0, 254.0	3.0, 47.0	166.0, 214.0	3.0, 3.0	185.0, 214.0	3.0, 26.5
Min, Max	NC, NC	NC, NC	198, 254	3, 47	166, 214	3, 3	166, 254	3, 47

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lactate Dehydrogenase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	0	5	3
Mean	NC	NC	226.3	25.3	175.5	NC	206.0	25.3
SD	NC	NC	40.81	34.95	6.36	NC	40.22	34.95
Median	NC	NC	217.0	16.0	175.5	NC	191.0	16.0
Q1, Q3	NC, NC	NC, NC	191.0, 271.0	-4.0, 64.0	171.0, 180.0	NC, NC	180.0, 217.0	-4.0, 64.0
Min, Max	NC, NC	NC, NC	191, 271	-4, 64	171, 180	NC, NC	171, 271	-4, 64
Cycle 13 Day 1								
Nx	0	0	1	1	2	0	3	1
Mean	NC	NC	190.0	-11.0	183.0	NC	185.3	-11.0
SD	NC	NC	NC	NC	12.73	NC	9.87	NC
Median	NC	NC	190.0	-11.0	183.0	NC	190.0	-11.0
Q1, Q3	NC, NC	NC, NC	190.0, 190.0	-11.0, -11.0	174.0, 192.0	NC, NC	174.0, 192.0	-11.0, -11.0
Min, Max	NC, NC	NC, NC	190, 190	-11, -11	174, 192	NC, NC	174, 192	-11, -11

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lactate Dehydrogenase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	0	2	1
Mean	NC	NC	203.0	2.0	184.0	NC	193.5	2.0
SD	NC	NC	NC	NC	NC	NC	13.44	NC
Median	NC	NC	203.0	2.0	184.0	NC	193.5	2.0
Q1, Q3	NC, NC	NC, NC	203.0, 203.0	2.0, 2.0	184.0, 184.0	NC, NC	184.0, 203.0	2.0, 2.0
Min, Max	NC, NC	NC, NC	203, 203	2, 2	184, 184	NC, NC	184, 203	2, 2
Cycle 17 Day 1								
Nx	0	0	1	1	1	0	2	1
Mean	NC	NC	179.0	-22.0	180.0	NC	179.5	-22.0
SD	NC	NC	NC	NC	NC	NC	0.71	NC
Median	NC	NC	179.0	-22.0	180.0	NC	179.5	-22.0
Q1, Q3	NC, NC	NC, NC	179.0, 179.0	-22.0, -22.0	180.0, 180.0	NC, NC	179.0, 180.0	-22.0, -22.0
Min, Max	NC, NC	NC, NC	179, 179	-22, -22	180, 180	NC, NC	179, 180	-22, -22

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lactate Dehydrogenase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	0	2	1
Mean	NC	NC	196.0	-5.0	166.0	NC	181.0	-5.0
SD	NC	NC	NC	NC	NC	NC	21.21	NC
Median	NC	NC	196.0	-5.0	166.0	NC	181.0	-5.0
Q1, Q3	NC, NC	NC, NC	196.0, 196.0	-5.0, -5.0	166.0, 166.0	NC, NC	166.0, 196.0	-5.0, -5.0
Min, Max	NC, NC	NC, NC	196, 196	-5, -5	166, 166	NC, NC	166, 196	-5, -5
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	189.0	-12.0	NC	NC	189.0	-12.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	189.0	-12.0	NC	NC	189.0	-12.0
Q1, Q3	NC, NC	NC, NC	189.0, 189.0	-12.0, -12.0	NC, NC	NC, NC	189.0, 189.0	-12.0, -12.0
Min, Max	NC, NC	NC, NC	189, 189	-12, -12	NC, NC	NC, NC	189, 189	-12, -12

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lactate Dehydrogenase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	173.0	-28.0	NC	NC	173.0	-28.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	173.0	-28.0	NC	NC	173.0	-28.0
Q1, Q3	NC, NC	NC, NC	173.0, 173.0	-28.0, -28.0	NC, NC	NC, NC	173.0, 173.0	-28.0, -28.0
Min, Max	NC, NC	NC, NC	173, 173	-28, -28	NC, NC	NC, NC	173, 173	-28, -28
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	197.0	-4.0	NC	NC	197.0	-4.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	197.0	-4.0	NC	NC	197.0	-4.0
Q1, Q3	NC, NC	NC, NC	197.0, 197.0	-4.0, -4.0	NC, NC	NC, NC	197.0, 197.0	-4.0, -4.0
Min, Max	NC, NC	NC, NC	197, 197	-4, -4	NC, NC	NC, NC	197, 197	-4, -4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Lactate Dehydrogenase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	7	5	14	12
Mean	395.0	150.7	230.0	10.3	267.6	-53.6	284.1	18.8
SD	182.20	123.49	51.39	41.44	253.23	61.45	197.99	108.47
Median	329.0	87.0	231.5	-7.0	177.0	-54.0	216.0	-7.0
Q1, Q3	255.0, 601.0	72.0, 293.0	186.0, 274.0	-12.0, 32.5	166.0, 238.0	-69.0, -30.0	177.0, 279.0	-42.0, 72.0
Min, Max	255, 601	72, 293	178, 279	-17, 72	96, 834	-142, 27	96, 834	-142, 293

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Gamma Glutamyl Transferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	3		4		6		13	
Mean	96.0		124.5		28.2		73.5	
SD	66.69		177.66		15.14		103.68	
Median	134.0		44.0		23.0		25.0	
Q1, Q3	19.0, 135.0		21.0, 228.0		18.0, 34.0		21.0, 67.0	
Min, Max	19, 135		21, 389		15, 56		15, 389	
Cycle 1 Day 6								
Nx	1	1	3	3	8	6	12	10
Mean	126.0	-9.0	48.0	11.7	31.5	1.3	43.5	3.4
SD	NC	NC	34.12	11.02	20.71	3.88	34.84	8.83
Median	126.0	-9.0	38.0	17.0	21.5	1.0	28.0	1.0
Q1, Q3	126.0, 126.0	-9.0, -9.0	20.0, 86.0	-1.0, 19.0	18.0, 48.5	0.0, 2.0	19.5, 63.5	-1.0, 8.0
Min, Max	126, 126	-9, -9	20, 86	-1, 19	12, 64	-4, 8	12, 126	-9, 19

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Gamma Glutamyl Transferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	2	2	2	2	6	5	10	9
Mean	136.5	2.0	45.0	1.0	31.0	0.0	54.9	0.7
SD	81.32	82.02	36.77	4.24	22.77	5.43	55.27	29.30
Median	136.5	2.0	45.0	1.0	18.5	0.0	30.5	0.0
Q1, Q3	79.0, 194.0	-56.0, 60.0	19.0, 71.0	-2.0, 4.0	18.0, 42.0	-2.0, 1.0	18.0, 73.0	-2.0, 4.0
Min, Max	79, 194	-56, 60	19, 71	-2, 4	16, 73	-7, 8	16, 194	-56, 60
Cycle 2 Day 1								
Nx	1	1	2	2	7	4	10	7
Mean	217.0	83.0	41.0	-3.0	34.7	2.5	54.2	12.4
SD	NC	NC	29.70	2.83	24.54	10.34	61.47	32.09
Median	217.0	83.0	41.0	-3.0	24.0	1.5	33.5	0.0
Q1, Q3	217.0, 217.0	83.0, 83.0	20.0, 62.0	-5.0, -1.0	16.0, 50.0	-4.5, 9.5	18.0, 62.0	-5.0, 16.0
Min, Max	217, 217	83, 83	20, 62	-5, -1	12, 80	-9, 16	12, 217	-9, 83

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Gamma Glutamyl Transferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	0	0	2	2	6	3	8	5
Mean	NC	NC	36.0	-8.0	34.8	1.7	35.1	-2.2
SD	NC	NC	29.70	2.83	17.15	1.15	18.34	5.54
Median	NC	NC	36.0	-8.0	29.5	1.0	29.5	1.0
Q1, Q3	NC, NC	NC, NC	15.0, 57.0	-10.0, -6.0	22.0, 47.0	1.0, 3.0	20.5, 52.0	-6.0, 1.0
Min, Max	NC, NC	NC, NC	15, 57	-10, -6	19, 62	1, 3	15, 62	-10, 3
Cycle 5 Day 1								
Nx	0	0	3	2	5	2	8	4
Mean	NC	NC	36.0	-10.0	34.4	0.5	35.0	-4.8
SD	NC	NC	16.37	9.90	18.99	0.71	16.84	8.34
Median	NC	NC	40.0	-10.0	22.0	0.5	31.0	-1.5
Q1, Q3	NC, NC	NC, NC	18.0, 50.0	-17.0, -3.0	22.0, 52.0	0.0, 1.0	20.0, 51.0	-10.0, 0.5
Min, Max	NC, NC	NC, NC	18, 50	-17, -3	18, 58	0, 1	18, 58	-17, 1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Gamma Glutamyl Transferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	3	2	5	2	8	4
Mean	NC	NC	62.0	29.0	38.6	0.0	47.4	14.5
SD	NC	NC	59.15	46.67	36.40	4.24	43.63	31.82
Median	NC	NC	40.0	29.0	24.0	0.0	27.0	0.0
Q1, Q3	NC, NC	NC, NC	17.0, 129.0	-4.0, 62.0	21.0, 30.0	-3.0, 3.0	19.0, 71.5	-3.5, 32.5
Min, Max	NC, NC	NC, NC	17, 129	-4, 62	15, 103	-3, 3	15, 129	-4, 62
Cycle 9 Day 1								
Nx	0	0	2	1	3	1	5	2
Mean	NC	NC	38.5	-5.0	20.3	3.0	27.6	-1.0
SD	NC	NC	31.82	NC	1.15	NC	18.78	5.66
Median	NC	NC	38.5	-5.0	21.0	3.0	21.0	-1.0
Q1, Q3	NC, NC	NC, NC	16.0, 61.0	-5.0, -5.0	19.0, 21.0	3.0, 3.0	19.0, 21.0	-5.0, 3.0
Min, Max	NC, NC	NC, NC	16, 61	-5, -5	19, 21	3, 3	16, 61	-5, 3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Gamma Glutamyl Transferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	1	2	0	5	1
Mean	NC	NC	39.3	-5.0	24.5	NC	33.4	-5.0
SD	NC	NC	29.87	NC	9.19	NC	23.09	NC
Median	NC	NC	29.0	-5.0	24.5	NC	29.0	-5.0
Q1, Q3	NC, NC	NC, NC	16.0, 73.0	-5.0, -5.0	18.0, 31.0	NC, NC	18.0, 31.0	-5.0, -5.0
Min, Max	NC, NC	NC, NC	16, 73	-5, -5	18, 31	NC, NC	16, 73	-5, -5
Cycle 13 Day 1								
Nx	0	0	1	0	2	0	3	0
Mean	NC	NC	24.0	NC	20.5	NC	21.7	NC
SD	NC	NC	NC	NC	3.54	NC	3.21	NC
Median	NC	NC	24.0	NC	20.5	NC	23.0	NC
Q1, Q3	NC, NC	NC, NC	24.0, 24.0	NC, NC	18.0, 23.0	NC, NC	18.0, 24.0	NC, NC
Min, Max	NC, NC	NC, NC	24, 24	NC, NC	18, 23	NC, NC	18, 24	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Gamma Glutamyl Transferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	0	1	0	2	0
Mean	NC	NC	26.0	NC	28.0	NC	27.0	NC
SD	NC	NC	NC	NC	NC	NC	1.41	NC
Median	NC	NC	26.0	NC	28.0	NC	27.0	NC
Q1, Q3	NC, NC	NC, NC	26.0, 26.0	NC, NC	28.0, 28.0	NC, NC	26.0, 28.0	NC, NC
Min, Max	NC, NC	NC, NC	26, 26	NC, NC	28, 28	NC, NC	26, 28	NC, NC
Cycle 17 Day 1								
Nx	0	0	1	0	1	0	2	0
Mean	NC	NC	26.0	NC	30.0	NC	28.0	NC
SD	NC	NC	NC	NC	NC	NC	2.83	NC
Median	NC	NC	26.0	NC	30.0	NC	28.0	NC
Q1, Q3	NC, NC	NC, NC	26.0, 26.0	NC, NC	30.0, 30.0	NC, NC	26.0, 30.0	NC, NC
Min, Max	NC, NC	NC, NC	26, 26	NC, NC	30, 30	NC, NC	26, 30	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Gamma Glutamyl Transferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	0	1	0	2	0
Mean	NC	NC	50.0	NC	32.0	NC	41.0	NC
SD	NC	NC	NC	NC	NC	NC	12.73	NC
Median	NC	NC	50.0	NC	32.0	NC	41.0	NC
Q1, Q3	NC, NC	NC, NC	50.0, 50.0	NC, NC	32.0, 32.0	NC, NC	32.0, 50.0	NC, NC
Min, Max	NC, NC	NC, NC	50, 50	NC, NC	32, 32	NC, NC	32, 50	NC, NC
Cycle 21 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	53.0	NC	NC	NC	53.0	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	53.0	NC	NC	NC	53.0	NC
Q1, Q3	NC, NC	NC, NC	53.0, 53.0	NC, NC	NC, NC	NC, NC	53.0, 53.0	NC, NC
Min, Max	NC, NC	NC, NC	53, 53	NC, NC	NC, NC	NC, NC	53, 53	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Gamma Glutamyl Transferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	51.0	NC	NC	NC	51.0	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	51.0	NC	NC	NC	51.0	NC
Q1, Q3	NC, NC	NC, NC	51.0, 51.0	NC, NC	NC, NC	NC, NC	51.0, 51.0	NC, NC
Min, Max	NC, NC	NC, NC	51, 51	NC, NC	NC, NC	NC, NC	51, 51	NC, NC
Cycle 25 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	31.0	NC	NC	NC	31.0	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	31.0	NC	NC	NC	31.0	NC
Q1, Q3	NC, NC	NC, NC	31.0, 31.0	NC, NC	NC, NC	NC, NC	31.0, 31.0	NC, NC
Min, Max	NC, NC	NC, NC	31, 31	NC, NC	NC, NC	NC, NC	31, 31	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Gamma Glutamyl Transferase (U/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	2	2	4	2	8	4	14	8
Mean	248.0	113.5	48.5	-3.0	35.5	-0.3	69.6	27.5
SD	200.82	201.53	33.79	1.41	45.89	6.18	101.24	92.94
Median	248.0	113.5	44.5	-3.0	19.5	1.5	23.5	-1.0
Q1, Q3	106.0, 390.0	-29.0, 256.0	20.5, 76.5	-4.0, -2.0	15.5, 27.5	-4.5, 4.0	17.0, 88.0	-6.5, 4.0
Min, Max	106, 390	-29, 256	17, 88	-4, -2	11, 148	-9, 5	11, 390	-29, 256

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	14.11		10.57		8.03		10.03	
SD	8.536		3.147		3.693		5.046	
Median	12.83		9.00		5.95		8.55	
Q1, Q3	8.55, 19.67		8.55, 13.68		5.13, 11.97		5.30, 13.68	
Min, Max	5.1, 25.7		6.8, 15.4		5.1, 13.7		5.1, 25.7	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	17.10	2.85	10.22	0.17	7.56	-0.47	9.90	0.25
SD	13.997	3.560	3.246	1.583	3.807	2.680	6.607	2.667
Median	13.68	1.71	10.13	0.50	7.70	-0.35	10.00	0.00
Q1, Q3	5.13, 32.49	0.00, 6.84	8.55, 13.68	-1.71, 1.71	5.13, 10.26	-1.71, 0.00	5.13, 13.68	-1.71, 1.71
Min, Max	5.1, 32.5	0.0, 6.8	5.1, 13.7	-1.7, 1.7	0.5, 13.7	-4.6, 5.1	0.5, 32.5	-4.6, 6.8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	13.68	-0.57	11.12	0.75	7.51	-0.03	9.86	0.08
SD	9.521	0.987	3.277	1.500	2.961	2.419	5.225	1.901
Median	11.97	0.00	10.28	0.00	6.84	0.00	8.55	0.00
Q1, Q3	5.13, 23.94	-1.71, 0.00	8.55, 13.70	0.00, 1.50	5.13, 8.55	-0.20, 1.71	6.40, 12.00	0.00, 1.71
Min, Max	5.1, 23.9	-1.7, 0.0	8.6, 15.4	0.0, 3.0	5.1, 13.7	-5.1, 1.7	5.1, 23.9	-5.1, 3.0
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	11.12	-4.28	9.34	-1.03	7.01	-0.25	8.26	-1.05
SD	8.464	6.046	1.671	3.104	3.339	1.708	3.839	2.932
Median	11.12	-4.28	10.13	-0.36	5.80	0.00	6.84	0.00
Q1, Q3	5.13, 17.10	-8.55, 0.00	8.42, 10.26	-3.42, 1.36	5.13, 8.55	-1.16, 1.01	5.13, 10.26	-1.71, 1.00
Min, Max	5.1, 17.1	-8.6, 0.0	6.8, 10.3	-5.1, 1.7	3.4, 13.7	-3.4, 1.7	3.4, 17.1	-8.6, 1.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	5.13	0.00	9.77	-0.61	6.70	-0.10	7.67	-0.27
SD	NC	NC	2.138	2.386	2.442	2.431	2.706	2.175
Median	5.13	0.00	10.13	-0.36	6.42	-0.30	6.84	0.00
Q1, Q3	5.13, 5.13	0.00, 0.00	8.42, 11.12	-2.57, 1.36	5.13, 8.55	-1.71, 1.71	5.13, 10.26	-1.71, 1.71
Min, Max	5.1, 5.1	0.0, 0.0	6.8, 12.0	-3.4, 1.7	3.4, 10.3	-3.4, 3.4	3.4, 12.0	-3.4, 3.4
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	5.13	0.00	8.66	-1.71	7.70	0.56	7.83	-0.40
SD	NC	NC	3.701	3.122	2.701	2.020	2.989	2.522
Median	5.13	0.00	9.63	-1.71	6.84	0.00	7.70	0.00
Q1, Q3	5.13, 5.13	0.00, 0.00	6.21, 11.12	-4.28, 0.86	6.00, 8.55	-0.60, 1.71	5.13, 10.26	-1.71, 1.71
Min, Max	5.1, 5.1	0.0, 0.0	3.4, 12.0	-5.1, 1.7	5.1, 12.0	-1.7, 3.4	3.4, 12.0	-5.1, 3.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	9.24	-1.14	9.21	2.07	9.22	0.65
SD	NC	NC	3.294	4.035	5.763	4.734	4.547	4.491
Median	NC	NC	9.41	-1.71	6.70	0.10	8.55	0.00
Q1, Q3	NC, NC	NC, NC	6.84, 11.63	-4.28, 2.00	5.13, 15.39	0.00, 1.71	5.13, 13.00	-1.71, 1.71
Min, Max	NC, NC	NC, NC	5.1, 13.0	-5.1, 4.0	3.4, 15.4	-1.7, 10.3	3.4, 15.4	-5.1, 10.3
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	9.12	-1.71	9.46	1.48	9.29	-0.11
SD	NC	NC	2.612	1.710	3.844	1.755	2.945	2.336
Median	NC	NC	8.55	-1.71	8.55	1.03	8.55	0.00
Q1, Q3	NC, NC	NC, NC	6.84, 11.97	-3.42, 0.00	6.16, 13.68	0.00, 3.42	6.84, 11.97	-1.71, 1.03
Min, Max	NC, NC	NC, NC	6.8, 12.0	-3.4, 0.0	6.2, 13.7	0.0, 3.4	6.2, 13.7	-3.4, 3.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	7.41	-3.42	8.55	-0.86	7.87	-2.39
SD	NC	NC	4.303	1.710	4.837	1.209	3.937	1.950
Median	NC	NC	6.84	-3.42	8.55	-0.86	6.84	-1.71
Q1, Q3	NC, NC	NC, NC	3.42, 11.97	-5.13, -1.71	5.13, 11.97	-1.71, 0.00	5.13, 11.97	-3.42, -1.71
Min, Max	NC, NC	NC, NC	3.4, 12.0	-5.1, -1.7	5.1, 12.0	-1.7, 0.0	3.4, 12.0	-5.1, 0.0
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	13.68	-1.71	7.70	-1.71	9.69	-1.71
SD	NC	NC	NC	NC	3.627	2.418	4.303	1.710
Median	NC	NC	13.68	-1.71	7.70	-1.71	10.26	-1.71
Q1, Q3	NC, NC	NC, NC	13.68, 13.68	-1.71, -1.71	5.13, 10.26	-3.42, 0.00	5.13, 13.68	-3.42, 0.00
Min, Max	NC, NC	NC, NC	13.7, 13.7	-1.7, -1.7	5.1, 10.3	-3.4, 0.0	5.1, 13.7	-3.4, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	10.26	-5.13	6.84	1.71	8.55	-1.71
SD	NC	NC	NC	NC	NC	NC	2.418	4.837
Median	NC	NC	10.26	-5.13	6.84	1.71	8.55	-1.71
Q1, Q3	NC, NC	NC, NC	10.26, 10.26	-5.13, -5.13	6.84, 6.84	1.71, 1.71	6.84, 10.26	-5.13, 1.71
Min, Max	NC, NC	NC, NC	10.3, 10.3	-5.1, -5.1	6.8, 6.8	1.7, 1.7	6.8, 10.3	-5.1, 1.7
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	15.39	0.00	5.13	0.00	10.26	0.00
SD	NC	NC	NC	NC	NC	NC	7.255	0.000
Median	NC	NC	15.39	0.00	5.13	0.00	10.26	0.00
Q1, Q3	NC, NC	NC, NC	15.39, 15.39	0.00, 0.00	5.13, 5.13	0.00, 0.00	5.13, 15.39	0.00, 0.00
Min, Max	NC, NC	NC, NC	15.4, 15.4	0.0, 0.0	5.1, 5.1	0.0, 0.0	5.1, 15.4	0.0, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	17.10	1.71	5.13	0.00	11.12	0.86
SD	NC	NC	NC	NC	NC	NC	8.464	1.209
Median	NC	NC	17.10	1.71	5.13	0.00	11.12	0.86
Q1, Q3	NC, NC	NC, NC	17.10, 17.10	1.71, 1.71	5.13, 5.13	0.00, 0.00	5.13, 17.10	0.00, 1.71
Min, Max	NC, NC	NC, NC	17.1, 17.1	1.7, 1.7	5.1, 5.1	0.0, 0.0	5.1, 17.1	0.0, 1.7
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	13.68	-1.71	NC	NC	13.68	-1.71
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	13.68	-1.71	NC	NC	13.68	-1.71
Q1, Q3	NC, NC	NC, NC	13.68, 13.68	-1.71, -1.71	NC, NC	NC, NC	13.68, 13.68	-1.71, -1.71
Min, Max	NC, NC	NC, NC	13.7, 13.7	-1.7, -1.7	NC, NC	NC, NC	13.7, 13.7	-1.7, -1.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	15.39	0.00	NC	NC	15.39	0.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	15.39	0.00	NC	NC	15.39	0.00
Q1, Q3	NC, NC	NC, NC	15.39, 15.39	0.00, 0.00	NC, NC	NC, NC	15.39, 15.39	0.00, 0.00
Min, Max	NC, NC	NC, NC	15.4, 15.4	0.0, 0.0	NC, NC	NC, NC	15.4, 15.4	0.0, 0.0
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	13.68	-1.71	NC	NC	13.68	-1.71
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	13.68	-1.71	NC	NC	13.68	-1.71
Q1, Q3	NC, NC	NC, NC	13.68, 13.68	-1.71, -1.71	NC, NC	NC, NC	13.68, 13.68	-1.71, -1.71
Min, Max	NC, NC	NC, NC	13.7, 13.7	-1.7, -1.7	NC, NC	NC, NC	13.7, 13.7	-1.7, -1.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Bilirubin (umol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	7	7	14	14
Mean	11.40	-2.85	9.52	-0.86	10.01	1.25	10.17	-0.23
SD	6.005	4.936	3.531	2.208	3.883	4.999	3.985	4.392
Median	11.97	0.00	9.63	-0.86	10.26	0.20	10.26	0.00
Q1, Q3	5.13, 17.10	-8.55, 0.00	7.07, 11.97	-2.57, 0.86	6.80, 13.68	-1.71, 5.13	6.80, 13.68	-1.71, 1.71
Min, Max	5.1, 17.1	-8.6, 0.0	5.1, 13.7	-3.4, 1.7	5.1, 15.4	-6.8, 8.6	5.1, 17.1	-8.6, 8.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Direct Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	3		6		10		19	
Mean	5.70		3.07		2.29		3.07	
SD	6.911		1.994		1.001		2.898	
Median	1.71		2.36		1.71		1.71	
Q1, Q3	1.71, 13.68		1.71, 3.42		1.71, 3.42		1.71, 3.42	
Min, Max	1.7, 13.7		1.7, 6.8		0.9, 3.4		0.9, 13.7	
Cycle 1 Day 6								
Nx	2	2	4	4	7	7	13	13
Mean	6.84	-0.86	3.32	0.00	1.98	-0.07	3.14	-0.17
SD	7.255	1.209	2.427	0.000	1.059	0.125	3.081	0.472
Median	6.84	-0.86	2.36	0.00	1.71	0.00	1.71	0.00
Q1, Q3	1.71, 11.97	-1.71, 0.00	1.71, 4.92	0.00, 0.00	1.30, 3.42	-0.20, 0.00	1.71, 3.42	0.00, 0.00
Min, Max	1.7, 12.0	-1.7, 0.0	1.7, 6.8	0.0, 0.0	0.6, 3.4	-0.3, 0.0	0.6, 12.0	-1.7, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Direct Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	1	1	2	2	6	6	9	9
Mean	11.97	-1.71	2.36	0.00	2.50	-0.03	3.52	-0.21
SD	NC	NC	0.912	0.000	1.022	0.082	3.287	0.566
Median	11.97	-1.71	2.36	0.00	2.57	0.00	3.00	0.00
Q1, Q3	11.97, 11.97	-1.71, -1.71	1.71, 3.00	0.00, 0.00	1.71, 3.42	0.00, 0.00	1.71, 3.42	0.00, 0.00
Min, Max	12.0, 12.0	-1.7, -1.7	1.7, 3.0	0.0, 0.0	1.3, 3.4	-0.2, 0.0	1.3, 12.0	-1.7, 0.0
Cycle 2 Day 1								
Nx	1	1	2	2	8	8	11	11
Mean	1.71	-11.97	2.86	0.50	2.44	-0.00	2.45	-1.00
SD	NC	NC	1.619	0.707	1.073	0.053	1.075	3.652
Median	1.71	-11.97	2.86	0.50	2.57	0.00	1.71	0.00
Q1, Q3	1.71, 1.71	-11.97, -11.97	1.71, 4.00	0.00, 1.00	1.56, 3.42	0.00, 0.00	1.71, 3.42	0.00, 0.00
Min, Max	1.7, 1.7	-12.0, -12.0	1.7, 4.0	0.0, 1.0	1.0, 3.4	-0.1, 0.1	1.0, 4.0	-12.0, 1.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Direct Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	0	0	2	2	6	6	8	8
Mean	NC	NC	2.36	0.00	2.48	-0.05	2.45	-0.04
SD	NC	NC	0.912	0.000	1.046	0.122	0.951	0.106
Median	NC	NC	2.36	0.00	2.57	0.00	2.36	0.00
Q1, Q3	NC, NC	NC, NC	1.71, 3.00	0.00, 0.00	1.71, 3.42	0.00, 0.00	1.71, 3.42	0.00, 0.00
Min, Max	NC, NC	NC, NC	1.7, 3.0	0.0, 0.0	1.2, 3.4	-0.3, 0.0	1.2, 3.4	-0.3, 0.0
Cycle 5 Day 1								
Nx	0	0	2	2	5	5	7	7
Mean	NC	NC	2.57	0.00	2.35	0.00	2.41	0.00
SD	NC	NC	1.209	0.000	0.979	0.000	0.945	0.000
Median	NC	NC	2.57	0.00	1.71	0.00	1.71	0.00
Q1, Q3	NC, NC	NC, NC	1.71, 3.42	0.00, 0.00	1.71, 3.42	0.00, 0.00	1.71, 3.42	0.00, 0.00
Min, Max	NC, NC	NC, NC	1.7, 3.4	0.0, 0.0	1.5, 3.4	0.0, 0.0	1.5, 3.4	0.0, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Direct Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	2	2	4	4	6	6
Mean	NC	NC	2.57	0.00	2.56	0.05	2.56	0.03
SD	NC	NC	1.209	0.000	0.990	0.100	0.938	0.082
Median	NC	NC	2.57	0.00	2.57	0.00	2.57	0.00
Q1, Q3	NC, NC	NC, NC	1.71, 3.42	0.00, 0.00	1.71, 3.42	0.00, 0.10	1.71, 3.42	0.00, 0.00
Min, Max	NC, NC	NC, NC	1.7, 3.4	0.0, 0.0	1.7, 3.4	0.0, 0.2	1.7, 3.4	0.0, 0.2
Cycle 9 Day 1								
Nx	0	0	2	2	3	3	5	5
Mean	NC	NC	2.57	0.00	2.85	0.00	2.74	0.00
SD	NC	NC	1.209	0.000	0.987	0.000	0.937	0.000
Median	NC	NC	2.57	0.00	3.42	0.00	3.42	0.00
Q1, Q3	NC, NC	NC, NC	1.71, 3.42	0.00, 0.00	1.71, 3.42	0.00, 0.00	1.71, 3.42	0.00, 0.00
Min, Max	NC, NC	NC, NC	1.7, 3.4	0.0, 0.0	1.7, 3.4	0.0, 0.0	1.7, 3.4	0.0, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Direct Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	2	1	1	4	3
Mean	NC	NC	2.85	0.00	3.42	0.00	2.99	0.00
SD	NC	NC	0.987	0.000	NC	NC	0.855	0.000
Median	NC	NC	3.42	0.00	3.42	0.00	3.42	0.00
Q1, Q3	NC, NC	NC, NC	1.71, 3.42	0.00, 0.00	3.42, 3.42	0.00, 0.00	2.57, 3.42	0.00, 0.00
Min, Max	NC, NC	NC, NC	1.7, 3.4	0.0, 0.0	3.4, 3.4	0.0, 0.0	1.7, 3.4	0.0, 0.0
Cycle 13 Day 1								
Nx	0	0	1	0	2	2	3	2
Mean	NC	NC	3.42	NC	3.42	0.00	3.42	0.00
SD	NC	NC	NC	NC	0.000	0.000	0.000	0.000
Median	NC	NC	3.42	NC	3.42	0.00	3.42	0.00
Q1, Q3	NC, NC	NC, NC	3.42, 3.42	NC, NC	3.42, 3.42	0.00, 0.00	3.42, 3.42	0.00, 0.00
Min, Max	NC, NC	NC, NC	3.4, 3.4	NC, NC	3.4, 3.4	0.0, 0.0	3.4, 3.4	0.0, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Direct Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	0	1	1	2	1
Mean	NC	NC	3.42	NC	3.42	0.00	3.42	0.00
SD	NC	NC	NC	NC	NC	NC	0.000	NC
Median	NC	NC	3.42	NC	3.42	0.00	3.42	0.00
Q1, Q3	NC, NC	NC, NC	3.42, 3.42	NC, NC	3.42, 3.42	0.00, 0.00	3.42, 3.42	0.00, 0.00
Min, Max	NC, NC	NC, NC	3.4, 3.4	NC, NC	3.4, 3.4	0.0, 0.0	3.4, 3.4	0.0, 0.0
Cycle 17 Day 1								
Nx	0	0	1	0	1	1	2	1
Mean	NC	NC	3.42	NC	3.42	0.00	3.42	0.00
SD	NC	NC	NC	NC	NC	NC	0.000	NC
Median	NC	NC	3.42	NC	3.42	0.00	3.42	0.00
Q1, Q3	NC, NC	NC, NC	3.42, 3.42	NC, NC	3.42, 3.42	0.00, 0.00	3.42, 3.42	0.00, 0.00
Min, Max	NC, NC	NC, NC	3.4, 3.4	NC, NC	3.4, 3.4	0.0, 0.0	3.4, 3.4	0.0, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Direct Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	3.42	NC	NC	NC	3.42	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	3.42	NC	NC	NC	3.42	NC
Q1, Q3	NC, NC	NC, NC	3.42, 3.42	NC, NC	NC, NC	NC, NC	3.42, 3.42	NC, NC
Min, Max	NC, NC	NC, NC	3.4, 3.4	NC, NC	NC, NC	NC, NC	3.4, 3.4	NC, NC
Cycle 21 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	3.42	NC	NC	NC	3.42	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	3.42	NC	NC	NC	3.42	NC
Q1, Q3	NC, NC	NC, NC	3.42, 3.42	NC, NC	NC, NC	NC, NC	3.42, 3.42	NC, NC
Min, Max	NC, NC	NC, NC	3.4, 3.4	NC, NC	NC, NC	NC, NC	3.4, 3.4	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Direct Bilirubin (umol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	3.42	NC	NC	NC	3.42	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	3.42	NC	NC	NC	3.42	NC
Q1, Q3	NC, NC	NC, NC	3.42, 3.42	NC, NC	NC, NC	NC, NC	3.42, 3.42	NC, NC
Min, Max	NC, NC	NC, NC	3.4, 3.4	NC, NC	NC, NC	NC, NC	3.4, 3.4	NC, NC
Cycle 25 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	3.42	NC	NC	NC	3.42	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	3.42	NC	NC	NC	3.42	NC
Q1, Q3	NC, NC	NC, NC	3.42, 3.42	NC, NC	NC, NC	NC, NC	3.42, 3.42	NC, NC
Min, Max	NC, NC	NC, NC	3.4, 3.4	NC, NC	NC, NC	NC, NC	3.4, 3.4	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Direct Bilirubin (umol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	2	2	3	3	5	5	10	10
Mean	1.71	-5.99	2.71	0.00	2.11	0.10	2.21	-1.15
SD	0.000	8.464	0.891	0.000	0.743	0.224	0.753	3.806
Median	1.71	-5.99	3.00	0.00	1.71	0.00	1.71	0.00
Q1, Q3	1.71, 1.71	-11.97, 0.00	1.71, 3.42	0.00, 0.00	1.71, 2.00	0.00, 0.00	1.71, 3.00	0.00, 0.00
Min, Max	1.7, 1.7	-12.0, 0.0	1.7, 3.4	0.0, 0.0	1.7, 3.4	0.0, 0.5	1.7, 3.4	-12.0, 0.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Albumin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	40.00		39.57		40.19		39.95	
SD	4.320		6.268		5.913		5.514	
Median	39.00		43.00		41.00		40.00	
Q1, Q3	37.00, 43.00		33.00, 45.00		35.00, 47.00		36.00, 45.00	
Min, Max	36.0, 46.0		30.0, 46.0		31.1, 47.0		30.0, 47.0	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	37.67	-0.33	38.67	-1.33	40.48	0.29	39.46	-0.32
SD	1.155	3.055	8.214	2.251	6.793	2.607	6.579	2.528
Median	37.00	-1.00	43.00	-0.50	41.50	0.75	40.00	0.00
Q1, Q3	37.00, 39.00	-3.00, 3.00	32.00, 44.00	-3.00, 0.00	36.00, 47.00	-2.00, 2.00	36.00, 44.00	-2.60, 1.00
Min, Max	37.0, 39.0	-3.0, 3.0	25.0, 45.0	-5.0, 1.0	30.2, 49.0	-4.0, 5.0	25.0, 49.0	-5.0, 5.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Albumin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	37.67	-0.33	43.50	-0.75	39.73	-2.00	40.36	-1.29
SD	2.309	4.163	3.697	3.096	7.608	4.435	5.968	3.811
Median	39.00	1.00	45.00	0.00	39.00	-2.00	39.00	-1.50
Q1, Q3	35.00, 39.00	-5.00, 3.00	41.50, 45.50	-3.00, 1.50	34.00, 44.00	-6.00, 2.00	36.00, 45.00	-5.00, 2.00
Min, Max	35.0, 39.0	-5.0, 3.0	38.0, 46.0	-5.0, 2.0	29.1, 52.0	-8.0, 5.0	29.1, 52.0	-8.0, 5.0
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	39.50	2.50	44.50	0.25	38.45	-2.16	40.33	-0.81
SD	0.707	2.121	2.646	1.708	7.806	3.674	6.488	3.383
Median	39.50	2.50	45.00	0.50	37.00	-2.15	40.50	0.50
Q1, Q3	39.00, 40.00	1.00, 4.00	42.50, 46.50	-1.00, 1.50	33.00, 45.50	-5.50, 1.50	35.00, 46.00	-3.50, 2.00
Min, Max	39.0, 40.0	1.0, 4.0	41.0, 47.0	-2.0, 2.0	27.6, 49.0	-7.0, 2.0	27.6, 49.0	-7.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Albumin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	40.00	2.00	44.25	0.00	41.33	-0.68	42.27	-0.19
SD	NC	NC	1.500	0.816	6.593	3.980	5.002	2.960
Median	40.00	2.00	44.00	0.00	40.50	0.45	43.00	0.00
Q1, Q3	40.00, 40.00	2.00, 2.00	43.00, 45.50	-0.50, 0.50	39.00, 48.00	-2.00, 2.00	40.00, 46.00	-1.00, 2.00
Min, Max	40.0, 40.0	2.0, 2.0	43.0, 46.0	-1.0, 1.0	31.0, 49.0	-8.0, 3.0	31.0, 49.0	-8.0, 3.0
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	41.00	3.00	45.25	1.00	42.32	1.30	43.36	1.35
SD	NC	NC	0.957	2.160	7.868	1.857	5.534	1.857
Median	41.00	3.00	45.50	1.50	41.00	1.00	44.50	1.50
Q1, Q3	41.00, 41.00	3.00, 3.00	44.50, 46.00	-0.50, 2.50	39.00, 49.00	0.50, 2.00	41.00, 46.00	0.50, 3.00
Min, Max	41.0, 41.0	3.0, 3.0	44.0, 46.0	-2.0, 3.0	31.6, 51.0	-1.0, 4.0	31.6, 51.0	-2.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Albumin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	45.75	1.50	40.28	-0.74	42.71	0.26
SD	NC	NC	3.096	3.109	7.842	1.743	6.531	2.557
Median	NC	NC	45.00	1.50	43.00	-1.00	44.00	0.00
Q1, Q3	NC, NC	NC, NC	43.50, 48.00	-1.00, 4.00	35.00, 46.00	-1.70, 1.00	43.00, 46.00	-1.70, 1.00
Min, Max	NC, NC	NC, NC	43.0, 50.0	-2.0, 5.0	29.4, 48.0	-3.0, 1.0	29.4, 50.0	-3.0, 5.0
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	47.00	2.33	39.67	-2.67	43.33	-0.17
SD	NC	NC	1.732	2.082	6.506	2.082	5.854	3.312
Median	NC	NC	46.00	3.00	40.00	-2.00	46.00	-0.50
Q1, Q3	NC, NC	NC, NC	46.00, 49.00	0.00, 4.00	33.00, 46.00	-5.00, -1.00	40.00, 46.00	-2.00, 3.00
Min, Max	NC, NC	NC, NC	46.0, 49.0	0.0, 4.0	33.0, 46.0	-5.0, -1.0	33.0, 49.0	-5.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Albumin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	46.00	1.33	44.00	-0.50	45.20	0.60
SD	NC	NC	1.000	2.517	4.243	0.707	2.490	2.074
Median	NC	NC	46.00	1.00	44.00	-0.50	46.00	0.00
Q1, Q3	NC, NC	NC, NC	45.00, 47.00	-1.00, 4.00	41.00, 47.00	-1.00, 0.00	45.00, 47.00	-1.00, 1.00
Min, Max	NC, NC	NC, NC	45.0, 47.0	-1.0, 4.0	41.0, 47.0	-1.0, 0.0	41.0, 47.0	-1.0, 4.0
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	48.00	3.00	44.50	0.00	45.67	1.00
SD	NC	NC	NC	NC	4.950	1.414	4.041	2.000
Median	NC	NC	48.00	3.00	44.50	0.00	48.00	1.00
Q1, Q3	NC, NC	NC, NC	48.00, 48.00	3.00, 3.00	41.00, 48.00	-1.00, 1.00	41.00, 48.00	-1.00, 3.00
Min, Max	NC, NC	NC, NC	48.0, 48.0	3.0, 3.0	41.0, 48.0	-1.0, 1.0	41.0, 48.0	-1.0, 3.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Albumin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	46.00	1.00	48.00	1.00	47.00	1.00
SD	NC	NC	NC	NC	NC	NC	1.414	0.000
Median	NC	NC	46.00	1.00	48.00	1.00	47.00	1.00
Q1, Q3	NC, NC	NC, NC	46.00, 46.00	1.00, 1.00	48.00, 48.00	1.00, 1.00	46.00, 48.00	1.00, 1.00
Min, Max	NC, NC	NC, NC	46.0, 46.0	1.0, 1.0	48.0, 48.0	1.0, 1.0	46.0, 48.0	1.0, 1.0
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	46.00	1.00	45.00	-2.00	45.50	-0.50
SD	NC	NC	NC	NC	NC	NC	0.707	2.121
Median	NC	NC	46.00	1.00	45.00	-2.00	45.50	-0.50
Q1, Q3	NC, NC	NC, NC	46.00, 46.00	1.00, 1.00	45.00, 45.00	-2.00, -2.00	45.00, 46.00	-2.00, 1.00
Min, Max	NC, NC	NC, NC	46.0, 46.0	1.0, 1.0	45.0, 45.0	-2.0, -2.0	45.0, 46.0	-2.0, 1.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Albumin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	50.00	5.00	47.00	0.00	48.50	2.50
SD	NC	NC	NC	NC	NC	NC	2.121	3.536
Median	NC	NC	50.00	5.00	47.00	0.00	48.50	2.50
Q1, Q3	NC, NC	NC, NC	50.00, 50.00	5.00, 5.00	47.00, 47.00	0.00, 0.00	47.00, 50.00	0.00, 5.00
Min, Max	NC, NC	NC, NC	50.0, 50.0	5.0, 5.0	47.0, 47.0	0.0, 0.0	47.0, 50.0	0.0, 5.0
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	46.00	1.00	NC	NC	46.00	1.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	46.00	1.00	NC	NC	46.00	1.00
Q1, Q3	NC, NC	NC, NC	46.00, 46.00	1.00, 1.00	NC, NC	NC, NC	46.00, 46.00	1.00, 1.00
Min, Max	NC, NC	NC, NC	46.0, 46.0	1.0, 1.0	NC, NC	NC, NC	46.0, 46.0	1.0, 1.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Albumin (g/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	45.00	0.00	NC	NC	45.00	0.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	45.00	0.00	NC	NC	45.00	0.00
Q1, Q3	NC, NC	NC, NC	45.00, 45.00	0.00, 0.00	NC, NC	NC, NC	45.00, 45.00	0.00, 0.00
Min, Max	NC, NC	NC, NC	45.0, 45.0	0.0, 0.0	NC, NC	NC, NC	45.0, 45.0	0.0, 0.0
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	48.00	3.00	NC	NC	48.00	3.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	48.00	3.00	NC	NC	48.00	3.00
Q1, Q3	NC, NC	NC, NC	48.00, 48.00	3.00, 3.00	NC, NC	NC, NC	48.00, 48.00	3.00, 3.00
Min, Max	NC, NC	NC, NC	48.0, 48.0	3.0, 3.0	NC, NC	NC, NC	48.0, 48.0	3.0, 3.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Albumin (g/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	34.00	-4.00	43.50	-0.75	38.08	-1.91	38.71	-2.02
SD	6.083	6.245	5.066	4.646	7.574	2.261	7.142	3.750
Median	31.00	-6.00	45.50	0.00	38.50	-2.10	41.00	-1.00
Q1, Q3	30.00, 41.00	-9.00, 3.00	40.50, 46.50	-4.00, 2.50	31.80, 45.00	-4.00, -0.50	31.00, 46.00	-4.10, 1.00
Min, Max	30.0, 41.0	-9.0, 3.0	36.0, 47.0	-7.0, 4.0	27.0, 47.0	-4.1, 2.0	27.0, 47.0	-9.0, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Cholesterol (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	4.08		4.88		4.10		4.36	
SD	0.876		1.522		1.261		1.293	
Median	4.38		4.68		4.34		4.40	
Q1, Q3	3.58, 4.58		3.96, 6.26		3.60, 5.07		3.93, 5.07	
Min, Max	2.8, 4.8		2.5, 6.7		1.1, 5.4		1.1, 6.7	
Cycle 1 Day 6								
Nx	2	2	5	5	10	10	17	17
Mean	3.41	-0.18	4.28	-0.28	4.77	0.67	4.47	0.29
SD	0.987	0.146	1.794	0.293	0.919	1.256	1.244	1.062
Median	3.41	-0.18	3.70	-0.34	4.63	0.10	4.29	0.00
Q1, Q3	2.72, 4.11	-0.28, -0.08	3.52, 5.72	-0.47, -0.26	3.93, 5.15	0.00, 1.40	3.78, 5.15	-0.28, 0.21
Min, Max	2.7, 4.1	-0.3, -0.1	2.0, 6.5	-0.5, 0.2	3.8, 6.6	-0.8, 3.2	2.0, 6.6	-0.8, 3.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Cholesterol (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	3	3	7	7	13	13
Mean	3.83	-0.16	5.15	-0.30	4.66	0.29	4.58	0.05
SD	1.035	0.318	1.148	0.427	0.713	0.640	0.938	0.571
Median	3.88	-0.03	5.48	-0.18	4.68	0.31	4.68	0.05
Q1, Q3	2.77, 4.84	-0.52, 0.08	3.88, 6.10	-0.78, 0.05	3.80, 5.17	-0.39, 0.78	3.88, 5.17	-0.39, 0.31
Min, Max	2.8, 4.8	-0.5, 0.1	3.9, 6.1	-0.8, 0.1	3.7, 5.6	-0.6, 1.3	2.8, 6.1	-0.8, 1.3
Cycle 2 Day 1								
Nx	2	2	3	3	8	8	13	13
Mean	4.46	0.69	5.86	0.25	4.68	0.11	4.92	0.23
SD	1.957	0.567	1.648	0.311	1.284	1.253	1.424	1.002
Median	4.46	0.69	6.21	0.16	4.86	0.15	4.94	0.20
Q1, Q3	3.08, 5.84	0.28, 1.09	4.06, 7.30	0.00, 0.60	3.57, 5.35	-0.67, 0.56	3.80, 5.84	0.00, 0.60
Min, Max	3.1, 5.8	0.3, 1.1	4.1, 7.3	0.0, 0.6	2.9, 6.9	-1.7, 2.5	2.9, 7.3	-1.7, 2.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Cholesterol (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	2.64	-0.16	5.90	0.13	4.85	0.50	5.03	0.31
SD	NC	NC	1.829	0.688	1.085	0.987	1.576	0.829
Median	2.64	-0.16	6.32	0.17	4.87	0.50	4.99	0.39
Q1, Q3	2.64, 2.64	-0.16, -0.16	4.67, 7.12	-0.39, 0.64	4.00, 5.38	-0.39, 0.65	3.44, 6.54	-0.39, 0.65
Min, Max	2.6, 2.6	-0.2, -0.2	3.3, 7.6	-0.7, 0.9	3.4, 6.5	-0.5, 2.2	2.6, 7.6	-0.7, 2.2
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	2.77	-0.03	5.77	0.01	5.22	1.03	5.20	0.51
SD	NC	NC	1.751	0.850	1.216	1.004	1.576	0.992
Median	2.77	-0.03	5.91	0.05	5.33	0.60	5.20	0.54
Q1, Q3	2.77, 2.77	-0.03, -0.03	4.37, 7.17	-0.69, 0.70	4.20, 5.92	0.59, 1.53	3.85, 6.75	-0.08, 0.90
Min, Max	2.8, 2.8	-0.0, -0.0	3.7, 7.6	-1.0, 0.9	3.9, 6.8	-0.1, 2.5	2.8, 7.6	-1.0, 2.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Cholesterol (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1								
Nx	0	0	4	4	5	5	9	9
Mean	NC	NC	5.77	0.00	4.62	0.43	5.13	0.24
SD	NC	NC	1.550	0.662	0.781	0.494	1.254	0.580
Median	NC	NC	6.20	-0.17	4.89	0.41	5.09	0.16
Q1, Q3	NC, NC	NC, NC	4.87, 6.67	-0.51, 0.52	4.34, 5.09	0.16, 0.70	4.34, 6.20	-0.20, 0.70
Min, Max	NC, NC	NC, NC	3.5, 7.1	-0.5, 0.9	3.4, 5.4	-0.2, 1.1	3.4, 7.1	-0.5, 1.1
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	5.78	0.33	4.52	0.20	5.15	0.26
SD	NC	NC	1.406	0.299	0.445	0.108	1.163	0.213
Median	NC	NC	6.21	0.16	4.37	0.23	4.69	0.19
Q1, Q3	NC, NC	NC, NC	4.22, 6.93	0.16, 0.67	4.16, 5.02	0.08, 0.28	4.22, 6.21	0.16, 0.28
Min, Max	NC, NC	NC, NC	4.2, 6.9	0.2, 0.7	4.2, 5.0	0.1, 0.3	4.2, 6.9	0.1, 0.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Cholesterol (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	5.74	0.28	4.42	0.09	5.21	0.21
SD	NC	NC	1.681	0.748	0.183	0.384	1.394	0.573
Median	NC	NC	5.79	-0.03	4.42	0.09	4.55	-0.03
Q1, Q3	NC, NC	NC, NC	4.03, 7.40	-0.26, 1.14	4.29, 4.55	-0.18, 0.36	4.29, 5.79	-0.18, 0.36
Min, Max	NC, NC	NC, NC	4.0, 7.4	-0.3, 1.1	4.3, 4.6	-0.2, 0.4	4.0, 7.4	-0.3, 1.1
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	5.22	-0.83	4.65	0.32	4.84	-0.06
SD	NC	NC	NC	NC	0.658	0.091	0.570	0.668
Median	NC	NC	5.22	-0.83	4.65	0.32	5.12	0.26
Q1, Q3	NC, NC	NC, NC	5.22, 5.22	-0.83, -0.83	4.19, 5.12	0.26, 0.39	4.19, 5.22	-0.83, 0.39
Min, Max	NC, NC	NC, NC	5.2, 5.2	-0.8, -0.8	4.2, 5.1	0.3, 0.4	4.2, 5.2	-0.8, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Cholesterol (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	6.18	0.13	5.64	0.91	5.91	0.52
SD	NC	NC	NC	NC	NC	NC	0.384	0.549
Median	NC	NC	6.18	0.13	5.64	0.91	5.91	0.52
Q1, Q3	NC, NC	NC, NC	6.18, 6.18	0.13, 0.13	5.64, 5.64	0.91, 0.91	5.64, 6.18	0.13, 0.91
Min, Max	NC, NC	NC, NC	6.2, 6.2	0.1, 0.1	5.6, 5.6	0.9, 0.9	5.6, 6.2	0.1, 0.9
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	6.00	-0.05	5.15	0.41	5.57	0.18
SD	NC	NC	NC	NC	NC	NC	0.603	0.329
Median	NC	NC	6.00	-0.05	5.15	0.41	5.57	0.18
Q1, Q3	NC, NC	NC, NC	6.00, 6.00	-0.05, -0.05	5.15, 5.15	0.41, 0.41	5.15, 6.00	-0.05, 0.41
Min, Max	NC, NC	NC, NC	6.0, 6.0	-0.1, -0.1	5.1, 5.1	0.4, 0.4	5.1, 6.0	-0.1, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Cholesterol (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	6.36	0.31	5.64	0.91	6.00	0.61
SD	NC	NC	NC	NC	NC	NC	0.512	0.421
Median	NC	NC	6.36	0.31	5.64	0.91	6.00	0.61
Q1, Q3	NC, NC	NC, NC	6.36, 6.36	0.31, 0.31	5.64, 5.64	0.91, 0.91	5.64, 6.36	0.31, 0.91
Min, Max	NC, NC	NC, NC	6.4, 6.4	0.3, 0.3	5.6, 5.6	0.9, 0.9	5.6, 6.4	0.3, 0.9
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.99	-1.06	NC	NC	4.99	-1.06
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.99	-1.06	NC	NC	4.99	-1.06
Q1, Q3	NC, NC	NC, NC	4.99, 4.99	-1.06, -1.06	NC, NC	NC, NC	4.99, 4.99	-1.06, -1.06
Min, Max	NC, NC	NC, NC	5.0, 5.0	-1.1, -1.1	NC, NC	NC, NC	5.0, 5.0	-1.1, -1.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Cholesterol (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.55	-1.50	NC	NC	4.55	-1.50
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.55	-1.50	NC	NC	4.55	-1.50
Q1, Q3	NC, NC	NC, NC	4.55, 4.55	-1.50, -1.50	NC, NC	NC, NC	4.55, 4.55	-1.50, -1.50
Min, Max	NC, NC	NC, NC	4.6, 4.6	-1.5, -1.5	NC, NC	NC, NC	4.6, 4.6	-1.5, -1.5
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	4.47	-1.58	NC	NC	4.47	-1.58
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	4.47	-1.58	NC	NC	4.47	-1.58
Q1, Q3	NC, NC	NC, NC	4.47, 4.47	-1.58, -1.58	NC, NC	NC, NC	4.47, 4.47	-1.58, -1.58
Min, Max	NC, NC	NC, NC	4.5, 4.5	-1.6, -1.6	NC, NC	NC, NC	4.5, 4.5	-1.6, -1.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Cholesterol (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	4.21	0.22	5.51	-0.26	4.49	0.14	4.70	0.05
SD	1.980	1.375	1.589	0.954	0.715	0.606	1.273	0.829
Median	3.39	-0.03	5.52	-0.44	4.59	0.09	4.60	-0.03
Q1, Q3	2.77, 6.47	-1.01, 1.71	4.25, 6.76	-0.86, 0.34	4.24, 4.75	-0.48, 0.75	3.67, 5.64	-0.50, 0.85
Min, Max	2.8, 6.5	-1.0, 1.7	3.7, 7.3	-1.2, 1.1	3.1, 5.6	-0.5, 0.9	2.8, 7.3	-1.2, 1.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Triglycerides (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	3		5		8		16	
Mean	1.099		1.147		1.685		1.407	
SD	0.4074		0.3690		0.5596		0.5360	
Median	0.869		1.005		1.710		1.315	
Q1, Q3	0.858, 1.569		0.994, 1.468		1.118, 2.252		0.999, 1.756	
Min, Max	0.86, 1.57		0.69, 1.58		1.03, 2.29		0.69, 2.29	
Cycle 1 Day 6								
Nx	2	1	4	4	9	8	15	13
Mean	1.377	0.000	1.064	-0.003	1.683	0.021	1.477	0.012
SD	0.2714	NC	0.3536	0.0910	0.5450	0.1237	0.5285	0.1056
Median	1.377	0.000	0.954	0.011	1.500	0.000	1.490	0.000
Q1, Q3	1.185, 1.569	0.000, 0.000	0.824, 1.304	-0.068, 0.062	1.264, 2.055	-0.028, 0.068	1.039, 1.874	-0.011, 0.034
Min, Max	1.19, 1.57	0.00, 0.00	0.78, 1.57	-0.12, 0.09	1.03, 2.55	-0.17, 0.26	0.78, 2.55	-0.17, 0.26

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Triglycerides (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	2	2	3	2	7	6	12	10
Mean	1.344	0.124	0.790	-0.147	1.426	-0.213	1.253	-0.132
SD	0.6227	0.1277	0.1077	0.0000	0.6847	0.3824	0.6099	0.3194
Median	1.344	0.124	0.847	-0.147	1.298	-0.119	0.982	-0.119
Q1, Q3	0.903, 1.784	0.034, 0.215	0.666, 0.858	-0.147, -0.147	0.780, 2.247	-0.271, -0.045	0.813, 1.569	-0.147, 0.034
Min, Max	0.90, 1.78	0.03, 0.21	0.67, 0.86	-0.15, -0.15	0.76, 2.48	-0.93, 0.20	0.67, 2.48	-0.93, 0.21
Cycle 2 Day 1								
Nx	1	1	2	1	8	6	11	8
Mean	0.745	-0.124	0.852	-0.135	1.776	0.203	1.514	0.120
SD	NC	NC	0.0080	NC	0.8831	0.3910	0.8645	0.3646
Median	0.745	-0.124	0.852	-0.135	1.629	0.203	1.276	0.051
Q1, Q3	0.745, 0.745	-0.124, -0.124	0.847, 0.858	-0.135, -0.135	1.033, 2.484	-0.102, 0.260	0.790, 2.484	-0.130, 0.231
Min, Max	0.75, 0.75	-0.12, -0.12	0.85, 0.86	-0.14, -0.14	0.73, 3.18	-0.24, 0.89	0.73, 3.18	-0.24, 0.89

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Triglycerides (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	0	0	4	2	6	5	10	7
Mean	NC	NC	1.246	-0.102	1.574	-0.117	1.443	-0.113
SD	NC	NC	0.7731	0.1118	0.6260	0.1012	0.6675	0.0947
Median	NC	NC	0.898	-0.102	1.733	-0.068	1.242	-0.068
Q1, Q3	NC, NC	NC, NC	0.807, 1.685	-0.181, -0.023	1.027, 2.123	-0.169, -0.045	0.824, 2.123	-0.181, -0.034
Min, Max	NC, NC	NC, NC	0.79, 2.40	-0.18, -0.02	0.67, 2.16	-0.27, -0.03	0.67, 2.40	-0.27, -0.02
Cycle 5 Day 1								
Nx	0	0	4	2	5	4	9	6
Mean	NC	NC	1.301	0.327	1.567	-0.181	1.449	-0.011
SD	NC	NC	0.7372	0.5109	0.7708	0.4929	0.7215	0.5165
Median	NC	NC	1.327	0.327	1.456	-0.169	1.456	-0.011
Q1, Q3	NC, NC	NC, NC	0.706, 1.897	-0.034, 0.689	1.084, 1.931	-0.559, 0.198	0.960, 1.931	-0.350, 0.384
Min, Max	NC, NC	NC, NC	0.45, 2.10	-0.03, 0.69	0.69, 2.68	-0.77, 0.38	0.45, 2.68	-0.77, 0.69

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Triglycerides (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	2	5	4	9	6
Mean	NC	NC	0.847	-0.198	1.545	-0.203	1.235	-0.201
SD	NC	NC	0.3574	0.1996	0.6898	0.5587	0.6490	0.4419
Median	NC	NC	0.802	-0.198	1.366	-0.073	1.300	-0.198
Q1, Q3	NC, NC	NC, NC	0.570, 1.124	-0.339, -0.056	1.321, 1.840	-0.649, 0.243	0.670, 1.366	-0.384, 0.237
Min, Max	NC, NC	NC, NC	0.49, 1.30	-0.34, -0.06	0.67, 2.53	-0.91, 0.25	0.49, 2.53	-0.91, 0.25
Cycle 9 Day 1								
Nx	0	0	3	2	3	3	6	5
Mean	NC	NC	0.960	-0.000	1.035	-0.824	0.997	-0.495
SD	NC	NC	0.1985	0.2714	0.2771	0.4666	0.2195	0.5754
Median	NC	NC	0.881	-0.000	1.016	-0.960	0.948	-0.305
Q1, Q3	NC, NC	NC, NC	0.813, 1.185	-0.192, 0.192	0.768, 1.321	-1.208, -0.305	0.813, 1.185	-0.960, -0.192
Min, Max	NC, NC	NC, NC	0.81, 1.19	-0.19, 0.19	0.77, 1.32	-1.21, -0.30	0.77, 1.32	-1.21, 0.19

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Triglycerides (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	2	2	2	5	4
Mean	NC	NC	1.189	0.299	1.852	0.175	1.454	0.237
SD	NC	NC	0.3397	0.4071	0.3353	1.1895	0.4663	0.7294
Median	NC	NC	1.016	0.299	1.852	0.175	1.581	0.299
Q1, Q3	NC, NC	NC, NC	0.971, 1.581	0.011, 0.587	1.614, 2.089	-0.666, 1.016	1.016, 1.614	-0.327, 0.802
Min, Max	NC, NC	NC, NC	0.97, 1.58	0.01, 0.59	1.61, 2.09	-0.67, 1.02	0.97, 2.09	-0.67, 1.02
Cycle 13 Day 1								
Nx	0	0	1	0	2	2	3	2
Mean	NC	NC	0.790	NC	1.445	-0.231	1.227	-0.231
SD	NC	NC	NC	NC	0.5109	0.3433	0.5229	0.3433
Median	NC	NC	0.790	NC	1.445	-0.231	1.084	-0.231
Q1, Q3	NC, NC	NC, NC	0.790, 0.790	NC, NC	1.084, 1.806	-0.474, 0.011	0.790, 1.806	-0.474, 0.011
Min, Max	NC, NC	NC, NC	0.79, 0.79	NC, NC	1.08, 1.81	-0.47, 0.01	0.79, 1.81	-0.47, 0.01

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Triglycerides (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	0	1	1	2	1
Mean	NC	NC	0.700	NC	2.179	-0.102	1.439	-0.102
SD	NC	NC	NC	NC	NC	NC	1.0458	NC
Median	NC	NC	0.700	NC	2.179	-0.102	1.439	-0.102
Q1, Q3	NC, NC	NC, NC	0.700, 0.700	NC, NC	2.179, 2.179	-0.102, -0.102	0.700, 2.179	-0.102, -0.102
Min, Max	NC, NC	NC, NC	0.70, 0.70	NC, NC	2.18, 2.18	-0.10, -0.10	0.70, 2.18	-0.10, -0.10
Cycle 17 Day 1								
Nx	0	0	1	0	1	1	2	1
Mean	NC	NC	0.858	NC	1.389	-0.892	1.123	-0.892
SD	NC	NC	NC	NC	NC	NC	0.3752	NC
Median	NC	NC	0.858	NC	1.389	-0.892	1.123	-0.892
Q1, Q3	NC, NC	NC, NC	0.858, 0.858	NC, NC	1.389, 1.389	-0.892, -0.892	0.858, 1.389	-0.892, -0.892
Min, Max	NC, NC	NC, NC	0.86, 0.86	NC, NC	1.39, 1.39	-0.89, -0.89	0.86, 1.39	-0.89, -0.89

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Triglycerides (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	0	1	1	2	1
Mean	NC	NC	0.779	NC	1.468	-0.813	1.123	-0.813
SD	NC	NC	NC	NC	NC	NC	0.4870	NC
Median	NC	NC	0.779	NC	1.468	-0.813	1.123	-0.813
Q1, Q3	NC, NC	NC, NC	0.779, 0.779	NC, NC	1.468, 1.468	-0.813, -0.813	0.779, 1.468	-0.813, -0.813
Min, Max	NC, NC	NC, NC	0.78, 0.78	NC, NC	1.47, 1.47	-0.81, -0.81	0.78, 1.47	-0.81, -0.81
Cycle 21 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	0.644	NC	NC	NC	0.644	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.644	NC	NC	NC	0.644	NC
Q1, Q3	NC, NC	NC, NC	0.644, 0.644	NC, NC	NC, NC	NC, NC	0.644, 0.644	NC, NC
Min, Max	NC, NC	NC, NC	0.64, 0.64	NC, NC	NC, NC	NC, NC	0.64, 0.64	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Triglycerides (mmol/L)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	0.677	NC	NC	NC	0.677	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.677	NC	NC	NC	0.677	NC
Q1, Q3	NC, NC	NC, NC	0.677, 0.677	NC, NC	NC, NC	NC, NC	0.677, 0.677	NC, NC
Min, Max	NC, NC	NC, NC	0.68, 0.68	NC, NC	NC, NC	NC, NC	0.68, 0.68	NC, NC
Cycle 25 Day 1								
Nx	0	0	1	0	0	0	1	0
Mean	NC	NC	0.565	NC	NC	NC	0.565	NC
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.565	NC	NC	NC	0.565	NC
Q1, Q3	NC, NC	NC, NC	0.565, 0.565	NC, NC	NC, NC	NC, NC	0.565, 0.565	NC, NC
Min, Max	NC, NC	NC, NC	0.56, 0.56	NC, NC	NC, NC	NC, NC	0.56, 0.56	NC, NC

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.2
Summary of Chemistry Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Triglycerides (mmol/L)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	2	2	4	2	8	6	14	10
Mean	1.264	0.045	1.409	0.203	1.478	-0.135	1.428	-0.032
SD	1.0857	0.5908	0.8572	0.3193	0.6864	0.4245	0.7209	0.4135
Median	1.264	0.045	1.202	0.203	1.485	-0.164	1.445	-0.073
Q1, Q3	0.497, 2.032	-0.373, 0.463	0.807, 2.011	-0.023, 0.429	0.796, 1.985	-0.305, 0.294	0.723, 2.032	-0.305, 0.339
Min, Max	0.50, 2.03	-0.37, 0.46	0.63, 2.60	-0.02, 0.43	0.71, 2.59	-0.81, 0.34	0.50, 2.60	-0.81, 0.46

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Activated Partial Thromboplastin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	36.68		32.11		28.81		31.41	
SD	9.921		6.723		2.182		6.290	
Median	32.85		30.30		27.95		30.00	
Q1, Q3	30.00, 43.35		27.00, 41.10		27.00, 30.90		27.00, 32.00	
Min, Max	30.0, 51.0		25.0, 42.0		26.8, 32.1		25.0, 51.0	
Cycle 1 Day 6								
Nx	3	3	6	6	9	9	18	18
Mean	45.03	6.13	30.37	-0.10	29.34	0.33	32.30	1.16
SD	25.092	14.787	5.340	2.400	3.090	1.891	11.023	5.864
Median	31.10	0.00	28.20	-0.15	29.00	0.00	29.35	0.00
Q1, Q3	30.00, 74.00	-4.60, 23.00	27.00, 31.00	-2.00, 0.60	27.00, 30.80	0.00, 0.30	27.00, 31.00	-0.30, 0.60
Min, Max	30.0, 74.0	-4.6, 23.0	27.0, 40.8	-2.9, 4.0	26.5, 36.2	-3.0, 4.1	26.5, 74.0	-4.6, 23.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Activated Partial Thromboplastin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	30.57	-8.33	28.05	-1.13	28.60	0.56	28.86	-1.83
SD	3.881	11.015	3.255	1.750	3.469	1.761	3.351	5.813
Median	30.00	-3.00	28.40	-1.25	27.00	0.00	27.90	-0.60
Q1, Q3	27.00, 34.70	-21.00, -1.00	25.50, 30.60	-2.50, 0.25	26.30, 29.10	-0.70, 2.00	27.00, 30.00	-2.00, 0.00
Min, Max	27.0, 34.7	-21.0, -1.0	24.0, 31.4	-3.0, 1.0	26.0, 36.0	-1.0, 3.9	24.0, 36.0	-21.0, 3.9
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	27.50	-5.35	27.73	-1.45	29.83	1.19	28.89	-0.50
SD	0.707	4.738	1.875	0.443	4.024	2.333	3.290	3.218
Median	27.50	-5.35	28.40	-1.40	29.35	1.20	28.40	-1.00
Q1, Q3	27.00, 28.00	-8.70, -2.00	26.50, 28.95	-1.80, -1.10	26.50, 32.55	-0.55, 2.75	27.00, 29.40	-2.00, 2.40
Min, Max	27.0, 28.0	-8.7, -2.0	25.0, 29.1	-2.0, -1.0	24.9, 36.9	-2.1, 4.8	24.9, 36.9	-8.7, 4.8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Activated Partial Thromboplastin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	36.40	0.70	28.43	-0.75	28.17	0.15	29.01	-0.13
SD	NC	NC	1.480	1.100	3.297	1.853	3.481	1.533
Median	36.40	0.70	28.10	-0.50	27.30	0.40	28.00	0.10
Q1, Q3	36.40, 36.40	0.70, 0.70	27.50, 29.35	-1.60, 0.10	25.00, 31.90	-2.00, 1.60	27.00, 31.90	-2.00, 0.70
Min, Max	36.4, 36.4	0.7, 0.7	27.0, 30.5	-2.2, 0.2	25.0, 32.5	-2.0, 2.5	25.0, 36.4	-2.2, 2.5
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	37.50	1.80	27.90	-1.28	28.22	0.00	29.02	-0.33
SD	NC	NC	1.738	1.360	2.440	1.420	3.543	1.573
Median	37.50	1.80	27.85	-1.05	28.00	0.10	28.35	-0.20
Q1, Q3	37.50, 37.50	1.80, 1.80	26.50, 29.30	-2.35, -0.20	26.90, 30.20	-0.70, 1.00	26.90, 30.20	-1.70, 1.00
Min, Max	37.5, 37.5	1.8, 1.8	26.0, 29.9	-3.0, 0.0	25.0, 31.0	-2.0, 1.6	25.0, 37.5	-3.0, 1.8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Activated Partial Thromboplastin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	4	4	8	8
Mean	NC	NC	28.43	-0.75	29.20	0.68	28.81	-0.04
SD	NC	NC	1.837	1.028	1.192	1.147	1.492	1.264
Median	NC	NC	28.65	-0.50	29.15	1.05	28.70	0.05
Q1, Q3	NC, NC	NC, NC	27.15, 29.70	-1.55, 0.05	28.20, 30.20	0.00, 1.35	28.15, 30.15	-1.00, 1.05
Min, Max	NC, NC	NC, NC	26.0, 30.4	-2.1, 0.1	28.0, 30.5	-1.0, 1.6	26.0, 30.5	-2.1, 1.6
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	28.90	-0.33	30.10	1.00	29.50	0.33
SD	NC	NC	1.900	1.041	1.308	2.615	1.600	1.924
Median	NC	NC	28.90	0.00	30.70	-0.20	29.80	-0.10
Q1, Q3	NC, NC	NC, NC	27.00, 30.80	-1.50, 0.50	28.60, 31.00	-0.80, 4.00	28.60, 30.80	-0.80, 0.50
Min, Max	NC, NC	NC, NC	27.0, 30.8	-1.5, 0.5	28.6, 31.0	-0.8, 4.0	27.0, 31.0	-1.5, 4.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Activated Partial Thromboplastin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	28.70	-0.53	31.30	1.15	29.74	0.14
SD	NC	NC	1.652	0.924	0.000	1.061	1.842	1.248
Median	NC	NC	28.80	0.00	31.30	1.15	30.30	0.00
Q1, Q3	NC, NC	NC, NC	27.00, 30.30	-1.60, 0.00	31.30, 31.30	0.40, 1.90	28.80, 31.30	0.00, 0.40
Min, Max	NC, NC	NC, NC	27.0, 30.3	-1.6, 0.0	31.3, 31.3	0.4, 1.9	27.0, 31.3	-1.6, 1.9
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	28.70	-1.70	29.75	-0.40	29.40	-0.83
SD	NC	NC	NC	NC	0.778	1.838	0.819	1.501
Median	NC	NC	28.70	-1.70	29.75	-0.40	29.20	-1.70
Q1, Q3	NC, NC	NC, NC	28.70, 28.70	-1.70, -1.70	29.20, 30.30	-1.70, 0.90	28.70, 30.30	-1.70, 0.90
Min, Max	NC, NC	NC, NC	28.7, 28.7	-1.7, -1.7	29.2, 30.3	-1.7, 0.9	28.7, 30.3	-1.7, 0.9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Activated Partial Thromboplastin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	27.80	-2.60	28.80	-0.60	28.30	-1.60
SD	NC	NC	NC	NC	NC	NC	0.707	1.414
Median	NC	NC	27.80	-2.60	28.80	-0.60	28.30	-1.60
Q1, Q3	NC, NC	NC, NC	27.80, 27.80	-2.60, -2.60	28.80, 28.80	-0.60, -0.60	27.80, 28.80	-2.60, -0.60
Min, Max	NC, NC	NC, NC	27.8, 27.8	-2.6, -2.6	28.8, 28.8	-0.6, -0.6	27.8, 28.8	-2.6, -0.6
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	28.00	-2.40	31.40	2.00	29.70	-0.20
SD	NC	NC	NC	NC	NC	NC	2.404	3.111
Median	NC	NC	28.00	-2.40	31.40	2.00	29.70	-0.20
Q1, Q3	NC, NC	NC, NC	28.00, 28.00	-2.40, -2.40	31.40, 31.40	2.00, 2.00	28.00, 31.40	-2.40, 2.00
Min, Max	NC, NC	NC, NC	28.0, 28.0	-2.4, -2.4	31.4, 31.4	2.0, 2.0	28.0, 31.4	-2.4, 2.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Activated Partial Thromboplastin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	27.40	-3.00	28.60	-0.80	28.00	-1.90
SD	NC	NC	NC	NC	NC	NC	0.849	1.556
Median	NC	NC	27.40	-3.00	28.60	-0.80	28.00	-1.90
Q1, Q3	NC, NC	NC, NC	27.40, 27.40	-3.00, -3.00	28.60, 28.60	-0.80, -0.80	27.40, 28.60	-3.00, -0.80
Min, Max	NC, NC	NC, NC	27.4, 27.4	-3.0, -3.0	28.6, 28.6	-0.8, -0.8	27.4, 28.6	-3.0, -0.8
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	28.20	-2.20	NC	NC	28.20	-2.20
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	28.20	-2.20	NC	NC	28.20	-2.20
Q1, Q3	NC, NC	NC, NC	28.20, 28.20	-2.20, -2.20	NC, NC	NC, NC	28.20, 28.20	-2.20, -2.20
Min, Max	NC, NC	NC, NC	28.2, 28.2	-2.2, -2.2	NC, NC	NC, NC	28.2, 28.2	-2.2, -2.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Activated Partial Thromboplastin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	26.70	-3.70	NC	NC	26.70	-3.70
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	26.70	-3.70	NC	NC	26.70	-3.70
Q1, Q3	NC, NC	NC, NC	26.70, 26.70	-3.70, -3.70	NC, NC	NC, NC	26.70, 26.70	-3.70, -3.70
Min, Max	NC, NC	NC, NC	26.7, 26.7	-3.7, -3.7	NC, NC	NC, NC	26.7, 26.7	-3.7, -3.7
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	26.50	-3.90	NC	NC	26.50	-3.90
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	26.50	-3.90	NC	NC	26.50	-3.90
Q1, Q3	NC, NC	NC, NC	26.50, 26.50	-3.90, -3.90	NC, NC	NC, NC	26.50, 26.50	-3.90, -3.90
Min, Max	NC, NC	NC, NC	26.5, 26.5	-3.9, -3.9	NC, NC	NC, NC	26.5, 26.5	-3.9, -3.9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Activated Partial Thromboplastin Time (sec)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	7	7	14	14
Mean	30.50	-8.40	28.78	-0.40	30.87	2.00	30.19	-0.91
SD	7.263	10.967	0.932	1.802	4.657	3.405	4.383	6.495
Median	31.00	-7.00	28.55	-0.65	29.30	2.00	29.15	-0.15
Q1, Q3	23.00, 37.50	-20.00, 1.80	28.05, 29.50	-1.65, 0.85	28.60, 31.40	-0.80, 2.50	28.10, 31.00	-1.10, 2.00
Min, Max	23.0, 37.5	-20.0, 1.8	28.0, 30.0	-2.3, 2.0	27.0, 41.0	-1.1, 8.9	23.0, 41.0	-20.0, 8.9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Intl. Normalized Ratio (RATIO)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	1.075		1.113		1.095		1.097	
SD	0.0500		0.2580		0.1425		0.1723	
Median	1.100		1.050		1.055		1.060	
Q1, Q3	1.050, 1.100		1.000, 1.100		1.000, 1.170		1.000, 1.100	
Min, Max	1.00, 1.10		0.90, 1.68		0.96, 1.43		0.90, 1.68	
Cycle 1 Day 6								
Nx	3	3	6	6	10	10	19	19
Mean	1.070	0.003	1.133	0.018	1.102	0.007	1.107	0.010
SD	0.0520	0.0950	0.2537	0.0765	0.1733	0.0613	0.1835	0.0674
Median	1.100	0.000	1.045	0.020	1.090	0.000	1.090	0.000
Q1, Q3	1.010, 1.100	-0.090, 0.100	1.000, 1.100	-0.040, 0.100	1.000, 1.110	-0.010, 0.000	1.000, 1.100	-0.030, 0.080
Min, Max	1.01, 1.10	-0.09, 0.10	0.97, 1.64	-0.09, 0.10	0.96, 1.56	-0.10, 0.13	0.96, 1.64	-0.10, 0.13

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Intl. Normalized Ratio (RATIO)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	1.087	0.020	1.103	0.075	1.089	-0.017	1.092	0.017
SD	0.0808	0.0346	0.0776	0.1041	0.1754	0.0450	0.1290	0.0727
Median	1.100	0.000	1.100	0.075	1.000	0.000	1.100	0.000
Q1, Q3	1.000, 1.160	0.000, 0.060	1.055, 1.150	0.000, 0.150	1.000, 1.120	-0.050, 0.020	1.000, 1.120	-0.020, 0.050
Min, Max	1.00, 1.16	0.00, 0.06	1.01, 1.20	-0.05, 0.20	0.94, 1.46	-0.10, 0.03	0.94, 1.46	-0.10, 0.20
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	1.070	0.020	1.020	-0.008	1.109	0.015	1.078	0.009
SD	0.0990	0.0283	0.0245	0.0096	0.2034	0.0800	0.1575	0.0604
Median	1.070	0.020	1.015	-0.005	1.050	0.000	1.025	0.000
Q1, Q3	1.000, 1.140	0.000, 0.040	1.000, 1.040	-0.015, 0.000	1.000, 1.115	-0.035, 0.065	1.000, 1.100	-0.020, 0.040
Min, Max	1.00, 1.14	0.00, 0.04	1.00, 1.05	-0.02, 0.00	0.95, 1.59	-0.10, 0.16	0.95, 1.59	-0.10, 0.16

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Intl. Normalized Ratio (RATIO)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	1.190	0.090	1.038	0.010	1.032	-0.025	1.048	-0.002
SD	NC	NC	0.0435	0.0115	0.0752	0.0589	0.0749	0.0547
Median	1.190	0.090	1.035	0.010	1.045	-0.025	1.070	0.000
Q1, Q3	1.190, 1.190	0.090, 0.090	1.000, 1.075	0.000, 0.020	1.000, 1.090	-0.070, 0.010	1.000, 1.090	-0.050, 0.020
Min, Max	1.19, 1.19	0.09, 0.09	1.00, 1.08	0.00, 0.02	0.91, 1.10	-0.10, 0.06	0.91, 1.19	-0.10, 0.09
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	1.140	0.040	1.043	0.015	1.062	-0.014	1.062	0.003
SD	NC	NC	0.0435	0.0597	0.0415	0.0371	0.0473	0.0467
Median	1.140	0.040	1.035	0.000	1.080	0.000	1.065	0.000
Q1, Q3	1.140, 1.140	0.040, 0.040	1.010, 1.075	-0.020, 0.050	1.040, 1.090	0.000, 0.000	1.020, 1.100	0.000, 0.010
Min, Max	1.14, 1.14	0.04, 0.04	1.00, 1.10	-0.04, 0.10	1.00, 1.10	-0.08, 0.01	1.00, 1.14	-0.08, 0.10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Intl. Normalized Ratio (RATIO)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	4	4	8	8
Mean	NC	NC	1.045	0.018	1.125	0.030	1.085	0.024
SD	NC	NC	0.0420	0.0556	0.0238	0.0648	0.0532	0.0563
Median	NC	NC	1.040	-0.005	1.125	0.015	1.100	0.000
Q1, Q3	NC, NC	NC, NC	1.015, 1.075	-0.015, 0.050	1.105, 1.145	-0.015, 0.075	1.040, 1.125	-0.015, 0.065
Min, Max	NC, NC	NC, NC	1.00, 1.10	-0.02, 0.10	1.10, 1.15	-0.03, 0.12	1.00, 1.15	-0.03, 0.12
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	1.007	-0.030	1.140	0.040	1.073	0.005
SD	NC	NC	0.0115	0.0265	0.0529	0.0794	0.0807	0.0653
Median	NC	NC	1.000	-0.040	1.120	0.070	1.060	-0.020
Q1, Q3	NC, NC	NC, NC	1.000, 1.020	-0.050, 0.000	1.100, 1.200	-0.050, 0.100	1.000, 1.120	-0.050, 0.070
Min, Max	NC, NC	NC, NC	1.00, 1.02	-0.05, 0.00	1.10, 1.20	-0.05, 0.10	1.00, 1.20	-0.05, 0.10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Intl. Normalized Ratio (RATIO)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	1.010	-0.027	1.160	0.060	1.070	0.008
SD	NC	NC	0.0173	0.0252	0.0707	0.0283	0.0903	0.0526
Median	NC	NC	1.000	-0.030	1.160	0.060	1.030	0.000
Q1, Q3	NC, NC	NC, NC	1.000, 1.030	-0.050, 0.000	1.110, 1.210	0.040, 0.080	1.000, 1.110	-0.030, 0.040
Min, Max	NC, NC	NC, NC	1.00, 1.03	-0.05, 0.00	1.11, 1.21	0.04, 0.08	1.00, 1.21	-0.05, 0.08
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	1.050	0.000	1.085	-0.015	1.073	-0.010
SD	NC	NC	NC	NC	0.0495	0.0495	0.0404	0.0361
Median	NC	NC	1.050	0.000	1.085	-0.015	1.050	0.000
Q1, Q3	NC, NC	NC, NC	1.050, 1.050	0.000, 0.000	1.050, 1.120	-0.050, 0.020	1.050, 1.120	-0.050, 0.020
Min, Max	NC, NC	NC, NC	1.05, 1.05	0.00, 0.00	1.05, 1.12	-0.05, 0.02	1.05, 1.12	-0.05, 0.02

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Intl. Normalized Ratio (RATIO)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	0.970	-0.080	1.190	0.020	1.080	-0.030
SD	NC	NC	NC	NC	NC	NC	0.1556	0.0707
Median	NC	NC	0.970	-0.080	1.190	0.020	1.080	-0.030
Q1, Q3	NC, NC	NC, NC	0.970, 0.970	-0.080, -0.080	1.190, 1.190	0.020, 0.020	0.970, 1.190	-0.080, 0.020
Min, Max	NC, NC	NC, NC	0.97, 0.97	-0.08, -0.08	1.19, 1.19	0.02, 0.02	0.97, 1.19	-0.08, 0.02
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	1.010	-0.040	1.170	0.000	1.090	-0.020
SD	NC	NC	NC	NC	NC	NC	0.1131	0.0283
Median	NC	NC	1.010	-0.040	1.170	0.000	1.090	-0.020
Q1, Q3	NC, NC	NC, NC	1.010, 1.010	-0.040, -0.040	1.170, 1.170	0.000, 0.000	1.010, 1.170	-0.040, 0.000
Min, Max	NC, NC	NC, NC	1.01, 1.01	-0.04, -0.04	1.17, 1.17	0.00, 0.00	1.01, 1.17	-0.04, 0.00

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Intl. Normalized Ratio (RATIO)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	1.000	-0.050	1.130	-0.040	1.065	-0.045
SD	NC	NC	NC	NC	NC	NC	0.0919	0.0071
Median	NC	NC	1.000	-0.050	1.130	-0.040	1.065	-0.045
Q1, Q3	NC, NC	NC, NC	1.000, 1.000	-0.050, -0.050	1.130, 1.130	-0.040, -0.040	1.000, 1.130	-0.050, -0.040
Min, Max	NC, NC	NC, NC	1.00, 1.00	-0.05, -0.05	1.13, 1.13	-0.04, -0.04	1.00, 1.13	-0.05, -0.04
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.960	-0.090	NC	NC	0.960	-0.090
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.960	-0.090	NC	NC	0.960	-0.090
Q1, Q3	NC, NC	NC, NC	0.960, 0.960	-0.090, -0.090	NC, NC	NC, NC	0.960, 0.960	-0.090, -0.090
Min, Max	NC, NC	NC, NC	0.96, 0.96	-0.09, -0.09	NC, NC	NC, NC	0.96, 0.96	-0.09, -0.09

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Intl. Normalized Ratio (RATIO)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	0.940	-0.110	NC	NC	0.940	-0.110
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	0.940	-0.110	NC	NC	0.940	-0.110
Q1, Q3	NC, NC	NC, NC	0.940, 0.940	-0.110, -0.110	NC, NC	NC, NC	0.940, 0.940	-0.110, -0.110
Min, Max	NC, NC	NC, NC	0.94, 0.94	-0.11, -0.11	NC, NC	NC, NC	0.94, 0.94	-0.11, -0.11
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	1.030	-0.020	NC	NC	1.030	-0.020
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	1.030	-0.020	NC	NC	1.030	-0.020
Q1, Q3	NC, NC	NC, NC	1.030, 1.030	-0.020, -0.020	NC, NC	NC, NC	1.030, 1.030	-0.020, -0.020
Min, Max	NC, NC	NC, NC	1.03, 1.03	-0.02, -0.02	NC, NC	NC, NC	1.03, 1.03	-0.02, -0.02

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Intl. Normalized Ratio (RATIO)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	1.080	0.013	1.018	-0.010	1.171	0.073	1.112	0.039
SD	0.0721	0.0231	0.0350	0.0271	0.3022	0.1664	0.2268	0.1247
Median	1.100	0.000	1.000	0.000	1.135	0.045	1.070	0.000
Q1, Q3	1.000, 1.140	0.000, 0.040	1.000, 1.035	-0.025, 0.005	0.980, 1.185	-0.030, 0.105	1.000, 1.140	-0.020, 0.090
Min, Max	1.00, 1.14	0.00, 0.04	1.00, 1.07	-0.05, 0.01	0.90, 1.87	-0.10, 0.44	0.90, 1.87	-0.10, 0.44

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	11.50		12.60		12.26		12.23	
SD	1.506		3.348		2.276		2.488	
Median	11.00		12.00		11.60		11.60	
Q1, Q3	10.60, 12.40		10.20, 13.00		10.50, 13.40		10.50, 13.00	
Min, Max	10.3, 13.7		9.6, 19.6		9.8, 17.3		9.6, 19.6	
Cycle 1 Day 6								
Nx	3	3	6	6	9	9	18	18
Mean	11.50	-0.13	12.97	0.08	12.60	0.12	12.54	0.07
SD	0.985	0.839	3.454	0.248	2.695	0.447	2.701	0.451
Median	11.20	0.30	12.45	0.05	11.80	0.00	11.90	0.05
Q1, Q3	10.70, 12.60	-1.10, 0.40	10.30, 13.40	-0.10, 0.20	10.90, 13.70	-0.10, 0.20	10.70, 13.40	-0.10, 0.30
Min, Max	10.7, 12.6	-1.1, 0.4	9.8, 19.4	-0.2, 0.5	9.7, 18.5	-0.3, 1.2	9.7, 19.4	-1.1, 1.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 14								
Nx	3	3	4	4	7	7	14	14
Mean	11.80	0.17	12.53	0.50	12.44	-0.00	12.33	0.18
SD	1.947	0.153	0.918	0.560	2.774	0.337	2.101	0.421
Median	11.10	0.20	12.65	0.35	12.00	0.00	12.00	0.15
Q1, Q3	10.30, 14.00	0.00, 0.30	11.75, 13.30	0.15, 0.85	10.40, 14.40	-0.30, 0.40	10.80, 13.30	0.00, 0.40
Min, Max	10.3, 14.0	0.0, 0.3	11.5, 13.3	0.0, 1.3	9.7, 17.7	-0.5, 0.4	9.7, 17.7	-0.5, 1.3
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	12.05	0.05	12.03	0.00	12.89	0.30	12.52	0.18
SD	2.475	0.071	1.377	0.141	2.968	0.619	2.417	0.482
Median	12.05	0.05	12.40	-0.05	12.30	0.05	12.40	0.00
Q1, Q3	10.30, 13.80	0.00, 0.10	11.05, 13.00	-0.10, 0.10	10.60, 14.30	-0.05, 0.55	10.40, 13.80	-0.10, 0.20
Min, Max	10.3, 13.8	0.0, 0.1	10.1, 13.2	-0.1, 0.2	9.8, 18.9	-0.3, 1.6	9.8, 18.9	-0.3, 1.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	4	4	6	6	11	11
Mean	14.30	0.60	12.50	0.48	12.03	-0.12	12.41	0.16
SD	NC	NC	1.417	0.377	1.690	0.299	1.573	0.439
Median	14.30	0.60	13.05	0.35	12.00	-0.10	13.00	0.20
Q1, Q3	14.30, 14.30	0.60, 0.60	11.70, 13.30	0.20, 0.75	10.60, 13.60	-0.40, 0.20	10.60, 13.60	-0.20, 0.50
Min, Max	14.3, 14.3	0.6, 0.6	10.4, 13.5	0.2, 1.0	9.8, 14.2	-0.5, 0.2	9.8, 14.3	-0.5, 1.0
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	13.80	0.10	12.03	0.00	12.02	-0.04	12.20	-0.01
SD	NC	NC	1.592	0.327	1.767	0.230	1.597	0.247
Median	13.80	0.10	12.45	0.00	11.70	0.00	12.45	0.00
Q1, Q3	13.80, 13.80	0.10, 0.10	10.90, 13.15	-0.20, 0.20	11.00, 13.60	-0.10, 0.10	11.00, 13.60	-0.10, 0.10
Min, Max	13.8, 13.8	0.1, 0.1	9.8, 13.4	-0.4, 0.4	9.8, 14.0	-0.4, 0.2	9.8, 14.0	-0.4, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	4	4	4	4	8	8
Mean	NC	NC	12.28	0.25	12.88	0.25	12.58	0.25
SD	NC	NC	1.459	0.520	1.713	0.387	1.508	0.424
Median	NC	NC	12.90	0.05	13.05	0.25	12.90	0.15
Q1, Q3	NC, NC	NC, NC	11.45, 13.10	-0.10, 0.60	11.45, 14.30	-0.05, 0.55	11.45, 13.65	-0.10, 0.55
Min, Max	NC, NC	NC, NC	10.1, 13.2	-0.1, 1.0	10.9, 14.5	-0.2, 0.7	10.1, 14.5	-0.2, 1.0
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	12.03	0.00	13.43	0.47	12.73	0.23
SD	NC	NC	1.677	0.173	1.002	0.945	1.454	0.659
Median	NC	NC	12.90	-0.10	13.80	0.80	13.00	0.05
Q1, Q3	NC, NC	NC, NC	10.10, 13.10	-0.10, 0.20	12.30, 14.20	-0.60, 1.20	12.30, 13.80	-0.10, 0.80
Min, Max	NC, NC	NC, NC	10.1, 13.1	-0.1, 0.2	12.3, 14.2	-0.6, 1.2	10.1, 14.2	-0.6, 1.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	12.13	0.10	14.25	0.35	12.98	0.20
SD	NC	NC	1.589	0.100	0.636	0.071	1.645	0.158
Median	NC	NC	13.00	0.10	14.25	0.35	13.10	0.20
Q1, Q3	NC, NC	NC, NC	10.30, 13.10	0.00, 0.20	13.80, 14.70	0.30, 0.40	13.00, 13.80	0.10, 0.30
Min, Max	NC, NC	NC, NC	10.3, 13.1	0.0, 0.2	13.8, 14.7	0.3, 0.4	10.3, 14.7	0.0, 0.4
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	13.20	0.30	13.75	-0.15	13.57	-0.00
SD	NC	NC	NC	NC	0.778	0.071	0.635	0.265
Median	NC	NC	13.20	0.30	13.75	-0.15	13.20	-0.10
Q1, Q3	NC, NC	NC, NC	13.20, 13.20	0.30, 0.30	13.20, 14.30	-0.20, -0.10	13.20, 14.30	-0.20, 0.30
Min, Max	NC, NC	NC, NC	13.2, 13.2	0.3, 0.3	13.2, 14.3	-0.2, -0.1	13.2, 14.3	-0.2, 0.3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	12.90	0.00	14.50	0.10	13.70	0.05
SD	NC	NC	NC	NC	NC	NC	1.131	0.071
Median	NC	NC	12.90	0.00	14.50	0.10	13.70	0.05
Q1, Q3	NC, NC	NC, NC	12.90, 12.90	0.00, 0.00	14.50, 14.50	0.10, 0.10	12.90, 14.50	0.00, 0.10
Min, Max	NC, NC	NC, NC	12.9, 12.9	0.0, 0.0	14.5, 14.5	0.1, 0.1	12.9, 14.5	0.0, 0.1
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	13.30	0.40	14.70	0.30	14.00	0.35
SD	NC	NC	NC	NC	NC	NC	0.990	0.071
Median	NC	NC	13.30	0.40	14.70	0.30	14.00	0.35
Q1, Q3	NC, NC	NC, NC	13.30, 13.30	0.40, 0.40	14.70, 14.70	0.30, 0.30	13.30, 14.70	0.30, 0.40
Min, Max	NC, NC	NC, NC	13.3, 13.3	0.4, 0.4	14.7, 14.7	0.3, 0.3	13.3, 14.7	0.3, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	13.10	0.20	14.40	0.00	13.75	0.10
SD	NC	NC	NC	NC	NC	NC	0.919	0.141
Median	NC	NC	13.10	0.20	14.40	0.00	13.75	0.10
Q1, Q3	NC, NC	NC, NC	13.10, 13.10	0.20, 0.20	14.40, 14.40	0.00, 0.00	13.10, 14.40	0.00, 0.20
Min, Max	NC, NC	NC, NC	13.1, 13.1	0.2, 0.2	14.4, 14.4	0.0, 0.0	13.1, 14.4	0.0, 0.2
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	12.70	-0.20	NC	NC	12.70	-0.20
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	12.70	-0.20	NC	NC	12.70	-0.20
Q1, Q3	NC, NC	NC, NC	12.70, 12.70	-0.20, -0.20	NC, NC	NC, NC	12.70, 12.70	-0.20, -0.20
Min, Max	NC, NC	NC, NC	12.7, 12.7	-0.2, -0.2	NC, NC	NC, NC	12.7, 12.7	-0.2, -0.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Time (sec)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	12.60	-0.30	NC	NC	12.60	-0.30
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	12.60	-0.30	NC	NC	12.60	-0.30
Q1, Q3	NC, NC	NC, NC	12.60, 12.60	-0.30, -0.30	NC, NC	NC, NC	12.60, 12.60	-0.30, -0.30
Min, Max	NC, NC	NC, NC	12.6, 12.6	-0.3, -0.3	NC, NC	NC, NC	12.6, 12.6	-0.3, -0.3
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	13.00	0.10	NC	NC	13.00	0.10
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	13.00	0.10	NC	NC	13.00	0.10
Q1, Q3	NC, NC	NC, NC	13.00, 13.00	0.10, 0.10	NC, NC	NC, NC	13.00, 13.00	0.10, 0.10
Min, Max	NC, NC	NC, NC	13.0, 13.0	0.1, 0.1	NC, NC	NC, NC	13.0, 13.0	0.1, 0.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.3
Summary of Coagulation Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: Prothrombin Time (sec)

	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
Visit	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	7	7	14	14
Mean	11.73	0.10	12.23	0.20	13.43	0.84	12.72	0.50
SD	1.960	0.500	1.646	0.392	3.795	1.376	2.904	1.037
Median	11.50	0.10	12.60	0.15	12.30	0.60	12.20	0.20
Q1, Q3	9.90, 13.80	-0.40, 0.60	11.00, 13.45	-0.10, 0.50	10.50, 14.40	0.00, 1.00	10.50, 13.80	0.00, 0.70
Min, Max	9.9, 13.8	-0.4, 0.6	10.0, 13.7	-0.2, 0.7	9.6, 21.1	-0.2, 3.8	9.6, 21.1	-0.4, 3.8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.4.1
Summary of Urinalysis Parameters (Dipstick)
(Safety Set)

	Dose Escalation			Total
	800 mg	1200 mg	1600 mg	
	N=4 n (%)	N=7 n (%)	N=10 n (%)	N=21 n (%)
Baseline				
Normal	1 (25.0)	5 (71.4)	5 (50.0)	11 (52.4)
Abnormal Clinically Non-Significant	0	2 (28.6)	5 (50.0)	7 (33.3)
Abnormal Clinically Significant	0	0	0	0
Cycle 1 Day 6				
Normal	1 (25.0)	5 (71.4)	3 (30.0)	9 (42.9)
Abnormal Clinically Non-Significant	2 (50.0)	1 (14.3)	6 (60.0)	9 (42.9)
Abnormal Clinically Significant	0	0	0	0
Cycle 1 Day 14				
Normal	1 (25.0)	4 (57.1)	2 (20.0)	7 (33.3)
Abnormal Clinically Non-Significant	2 (50.0)	0	5 (50.0)	7 (33.3)
Abnormal Clinically Significant	0	0	0	0
Cycle 2 Day 1				
Normal	0	3 (42.9)	4 (40.0)	7 (33.3)
Abnormal Clinically Non-Significant	1 (25.0)	1 (14.3)	3 (30.0)	5 (23.8)
Abnormal Clinically Significant	0	0	0	0

N = number of patients in the analysis set; n = number of patients in the specified category; Percentage (%) = $n/N * 100$.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.4.1
Summary of Urinalysis Parameters (Dipstick)
(Safety Set)

	Dose Escalation			Total
	800 mg	1200 mg	1600 mg	
	N=4 n (%)	N=7 n (%)	N=10 n (%)	N=21 n (%)
Cycle 3 Day 1				
Normal	1 (25.0)	4 (57.1)	4 (40.0)	9 (42.9)
Abnormal Clinically Non-Significant	0	0	2 (20.0)	2 (9.5)
Abnormal Clinically Significant	0	0	0	0
Cycle 5 Day 1				
Normal	1 (25.0)	4 (57.1)	0	5 (23.8)
Abnormal Clinically Non-Significant	0	0	5 (50.0)	5 (23.8)
Abnormal Clinically Significant	0	0	0	0
Cycle 7 Day 1				
Normal	0	3 (42.9)	0	3 (14.3)
Abnormal Clinically Non-Significant	0	0	4 (40.0)	4 (19.0)
Abnormal Clinically Significant	0	0	0	0
Cycle 9 Day 1				
Normal	0	2 (28.6)	1 (10.0)	3 (14.3)
Abnormal Clinically Non-Significant	0	1 (14.3)	2 (20.0)	3 (14.3)
Abnormal Clinically Significant	0	0	0	0

N = number of patients in the analysis set; n = number of patients in the specified category; Percentage (%) = $n/N * 100$.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.4.1
Summary of Urinalysis Parameters (Dipstick)
(Safety Set)

	Dose Escalation			Total
	800 mg	1200 mg	1600 mg	
	N=4 n (%)	N=7 n (%)	N=10 n (%)	N=21 n (%)
Cycle 11 Day 1				
Normal	0	2 (28.6)	0	2 (9.5)
Abnormal Clinically Non-Significant	0	1 (14.3)	1 (10.0)	2 (9.5)
Abnormal Clinically Significant	0	0	1 (10.0)	1 (4.8)
Cycle 13 Day 1				
Normal	0	1 (14.3)	2 (20.0)	3 (14.3)
Abnormal Clinically Non-Significant	0	0	0	0
Abnormal Clinically Significant	0	0	0	0
Cycle 15 Day 1				
Normal	0	1 (14.3)	1 (10.0)	2 (9.5)
Abnormal Clinically Non-Significant	0	0	0	0
Abnormal Clinically Significant	0	0	0	0
Cycle 17 Day 1				
Normal	0	1 (14.3)	1 (10.0)	2 (9.5)
Abnormal Clinically Non-Significant	0	0	0	0
Abnormal Clinically Significant	0	0	0	0

N = number of patients in the analysis set; n = number of patients in the specified category; Percentage (%) = $n/N * 100$.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.4.1
Summary of Urinalysis Parameters (Dipstick)
(Safety Set)

	Dose Escalation			Total
	800 mg	1200 mg	1600 mg	
	N=4 n (%)	N=7 n (%)	N=10 n (%)	N=21 n (%)
Cycle 19 Day 1				
Normal	0	0	0	0
Abnormal Clinically Non-Significant	0	1 (14.3)	1 (10.0)	2 (9.5)
Abnormal Clinically Significant	0	0	0	0
Cycle 21 Day 1				
Normal	0	1 (14.3)	0	1 (4.8)
Abnormal Clinically Non-Significant	0	0	0	0
Abnormal Clinically Significant	0	0	0	0
Cycle 23 Day 1				
Normal	0	1 (14.3)	0	1 (4.8)
Abnormal Clinically Non-Significant	0	0	0	0
Abnormal Clinically Significant	0	0	0	0
Cycle 25 Day 1				
Normal	0	1 (14.3)	0	1 (4.8)
Abnormal Clinically Non-Significant	0	0	0	0
Abnormal Clinically Significant	0	0	0	0

N = number of patients in the analysis set; n = number of patients in the specified category; Percentage (%) = $n/N * 100$.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.4.1
Summary of Urinalysis Parameters (Dipstick)
(Safety Set)

	Dose Escalation			Total
	800 mg	1200 mg	1600 mg	
	N=4 n (%)	N=7 n (%)	N=10 n (%)	N=21 n (%)
End of Treatment				
Normal	1 (25.0)	2 (28.6)	3 (30.0)	6 (28.6)
Abnormal Clinically Non-Significant	0	2 (28.6)	3 (30.0)	5 (23.8)
Abnormal Clinically Significant	0	0	0	0

N = number of patients in the analysis set; n = number of patients in the specified category; Percentage (%) = $n/N * 100$.
Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.5
Summary of Testosterone (nmol/L) by Treatment Group and Timepoint
(Safety Set)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	1		2		4		7	
Mean	10.40		19.12		22.54		19.83	
SD	NC		26.896		10.779		14.090	
Median	10.40		19.12		22.54		17.33	
Q1, Q3	10.40, 10.40		0.10, 38.14		13.87, 31.20		10.40, 34.67	
Min, Max	10.4, 10.4		0.1, 38.1		10.4, 34.7		0.1, 38.1	
Cycle 2 Day 1								
Nx	1	1	2	2	4	4	7	7
Mean	10.40	0.00	13.92	-5.20	33.80	11.27	24.78	4.95
SD	NC	NC	19.542	7.355	37.807	29.605	30.107	22.634
Median	10.40	0.00	13.92	-5.20	17.33	-1.73	13.87	0.00
Q1, Q3	10.40, 10.40	0.00, 0.00	0.10, 27.74	-10.40, 0.00	12.13, 55.47	-5.20, 27.74	10.40, 27.74	-6.93, 0.00
Min, Max	10.4, 10.4	0.0, 0.0	0.1, 27.7	-10.4, 0.0	10.4, 90.1	-6.9, 55.5	0.1, 90.1	-10.4, 55.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.5
Summary of Testosterone (nmol/L) by Treatment Group and Timepoint
(Safety Set)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1								
Nx	1	1	2	2	3	3	6	6
Mean	10.40	0.00	20.85	1.73	41.60	17.33	29.49	9.25
SD	NC	NC	29.348	2.452	39.983	30.025	31.662	20.994
Median	10.40	0.00	20.85	1.73	27.74	0.00	19.07	0.00
Q1, Q3	10.40, 10.40	0.00, 0.00	0.10, 41.60	0.00, 3.47	10.40, 86.67	0.00, 52.00	10.40, 41.60	0.00, 3.47
Min, Max	10.4, 10.4	0.0, 0.0	0.1, 41.6	0.0, 3.5	10.4, 86.7	0.0, 52.0	0.1, 86.7	0.0, 52.0
Cycle 5 Day 1								
Nx	1	1	2	2	3	3	6	6
Mean	10.40	0.00	8.72	-10.40	20.80	-3.47	15.04	-5.20
SD	NC	NC	12.187	14.709	10.401	3.467	10.639	8.131
Median	10.40	0.00	8.72	-10.40	20.80	-3.47	13.87	-1.73
Q1, Q3	10.40, 10.40	0.00, 0.00	0.10, 17.33	-20.80, 0.00	10.40, 31.20	-6.93, 0.00	10.40, 20.80	-6.93, 0.00
Min, Max	10.4, 10.4	0.0, 0.0	0.1, 17.3	-20.8, 0.0	10.4, 31.2	-6.9, 0.0	0.1, 31.2	-20.8, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.5
Summary of Testosterone (nmol/L) by Treatment Group and Timepoint
(Safety Set)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1								
Nx	0	0	2	2	3	3	5	5
Mean	NC	NC	10.45	-8.67	21.96	-2.31	17.35	-4.85
SD	NC	NC	14.639	12.258	10.592	2.002	12.222	7.189
Median	NC	NC	10.45	-8.67	24.27	-3.47	20.80	-3.47
Q1, Q3	NC, NC	NC, NC	0.10, 20.80	-17.33, 0.00	10.40, 31.20	-3.47, 0.00	10.40, 24.27	-3.47, 0.00
Min, Max	NC, NC	NC, NC	0.1, 20.8	-17.3, 0.0	10.4, 31.2	-3.5, 0.0	0.1, 31.2	-17.3, 0.0
Cycle 9 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	27.74	-10.40	15.60	-3.47	19.65	-5.78
SD	NC	NC	NC	NC	7.355	4.903	8.725	5.296
Median	NC	NC	27.74	-10.40	15.60	-3.47	20.80	-6.93
Q1, Q3	NC, NC	NC, NC	27.74, 27.74	-10.40, -10.40	10.40, 20.80	-6.93, 0.00	10.40, 27.74	-10.40, 0.00
Min, Max	NC, NC	NC, NC	27.7, 27.7	-10.4, -10.4	10.4, 20.8	-6.9, 0.0	10.4, 27.7	-10.4, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.5
Summary of Testosterone (nmol/L) by Treatment Group and Timepoint
(Safety Set)

Visit	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	24.27	-13.87	10.40	0.00	17.33	-6.93
SD	NC	NC	NC	NC	NC	NC	9.806	9.806
Median	NC	NC	24.27	-13.87	10.40	0.00	17.33	-6.93
Q1, Q3	NC, NC	NC, NC	24.27, 24.27	-13.87, -13.87	10.40, 10.40	0.00, 0.00	10.40, 24.27	-13.87, 0.00
Min, Max	NC, NC	NC, NC	24.3, 24.3	-13.9, -13.9	10.4, 10.4	0.0, 0.0	10.4, 24.3	-13.9, 0.0
Cycle 13 Day 1								
Nx	0	0	0	0	1	1	1	1
Mean	NC	NC	NC	NC	10.40	0.00	10.40	0.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	NC	NC	10.40	0.00	10.40	0.00
Q1, Q3	NC, NC	NC, NC	NC, NC	NC, NC	10.40, 10.40	0.00, 0.00	10.40, 10.40	0.00, 0.00
Min, Max	NC, NC	NC, NC	NC, NC	NC, NC	10.4, 10.4	0.0, 0.0	10.4, 10.4	0.0, 0.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-3.5
Summary of Testosterone (nmol/L) by Treatment Group and Timepoint
(Safety Set)

Visit	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
End of Treatment								
Nx	0	0	2	2	5	4	7	6
Mean	NC	NC	19.12	0.00	25.66	-3.47	23.79	-2.31
SD	NC	NC	26.896	0.000	18.606	6.330	19.014	5.220
Median	NC	NC	19.12	0.00	17.33	-3.47	17.33	0.00
Q1, Q3	NC, NC	NC, NC	0.10, 38.14	0.00, 0.00	10.40, 38.14	-8.67, 1.73	10.40, 38.14	-6.93, 0.00
Min, Max	NC, NC	NC, NC	0.1, 38.1	0.0, 0.0	10.4, 52.0	-10.4, 3.5	0.1, 52.0	-10.4, 3.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	127.3		128.4		127.7		127.9	
SD	25.05		17.85		19.33		18.92	
Median	126.5		123.0		121.5		123.0	
Q1, Q3	107.0, 147.5		114.0, 149.0		115.0, 138.0		114.0, 139.0	
Min, Max	100, 156		111, 156		106, 166		100, 166	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	133.5	6.3	126.6	-1.9	125.6	-2.1	127.4	-0.4
SD	20.42	9.18	19.49	5.98	13.62	13.21	16.41	10.63
Median	139.0	7.5	128.0	-3.0	123.0	2.5	125.0	1.0
Q1, Q3	118.0, 149.0	0.0, 12.5	107.0, 150.0	-8.0, 4.0	116.0, 132.0	-5.0, 6.0	113.0, 148.0	-6.0, 6.0
Min, Max	106, 150	-6, 16	106, 153	-8, 7	111, 149	-34, 11	106, 153	-34, 16

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4	Change from baseline	N=7	Change from baseline	N=10	Change from baseline	Value	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	9	9	20	20
Mean	127.8	0.5	124.4	-4.0	130.0	5.1	127.6	1.0
SD	24.51	14.39	20.65	15.12	13.95	10.42	17.83	12.96
Median	126.0	1.5	128.0	-3.0	126.0	10.0	127.0	1.5
Q1, Q3	110.5, 145.0	-9.0, 10.0	105.0, 143.0	-14.0, 7.0	122.0, 136.0	0.0, 11.0	115.0, 139.5	-7.0, 11.0
Min, Max	100, 159	-18, 17	100, 156	-27, 20	111, 153	-16, 16	100, 159	-27, 20
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	120.3	-3.0	121.2	-3.8	121.7	-1.8	121.3	-2.7
SD	32.32	3.61	15.72	9.66	12.06	5.85	16.25	6.78
Median	112.0	-2.0	118.5	-2.0	121.0	-2.0	119.0	-2.0
Q1, Q3	93.0, 156.0	-7.0, 0.0	108.0, 138.0	-11.0, 0.0	114.0, 132.0	-3.0, 3.0	111.0, 135.0	-7.0, 2.0
Min, Max	93, 156	-7, 0	103, 141	-18, 10	103, 140	-13, 5	93, 156	-18, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 6, 1 Hour Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	116.7	-6.7	118.7	-6.3	127.2	-1.9	122.6	-4.2
SD	25.58	10.41	15.88	14.09	16.88	14.24	17.56	13.12
Median	119.0	-10.0	119.5	-4.5	121.0	-1.0	121.0	-1.5
Q1, Q3	90.0, 141.0	-15.0, 5.0	105.0, 130.0	-16.0, 7.0	118.0, 133.0	-4.0, 0.0	109.0, 133.0	-10.0, 5.0
Min, Max	90, 141	-15, 5	99, 139	-28, 8	108, 154	-33, 16	90, 154	-33, 16
Cycle 1 Day 6, 4 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	126.0	2.7	122.7	-2.3	123.1	-6.0	123.4	-3.3
SD	32.14	21.96	11.94	15.49	21.17	10.52	19.39	13.78
Median	142.0	-9.0	120.0	0.0	115.0	-11.0	115.0	-2.5
Q1, Q3	89.0, 147.0	-11.0, 28.0	113.0, 134.0	-2.0, 3.0	110.0, 142.0	-14.0, -1.0	110.0, 142.0	-12.0, 1.0
Min, Max	89, 147	-11, 28	110, 139	-31, 16	103, 155	-15, 17	89, 155	-31, 28

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4	Change from baseline	N=7	Change from baseline	N=10	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	7	7	14	14
Mean	123.0	-0.3	133.0	2.0	121.9	-4.4	125.3	-1.7
SD	19.47	14.36	16.67	9.02	14.02	15.68	15.46	13.14
Median	116.0	-6.0	135.0	-1.0	122.0	-8.0	123.5	-4.0
Q1, Q3	108.0, 145.0	-11.0, 16.0	121.5, 144.5	-4.0, 8.0	107.0, 136.0	-14.0, 10.0	111.0, 138.0	-9.0, 10.0
Min, Max	108, 145	-11, 16	111, 151	-5, 15	104, 142	-30, 16	104, 151	-30, 16
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	126.7	3.3	126.5	-4.5	115.7	-8.7	121.5	-4.6
SD	26.10	6.11	19.54	21.02	15.90	8.07	18.61	12.95
Median	124.0	2.0	129.5	-8.5	111.0	-10.5	115.0	-3.0
Q1, Q3	102.0, 154.0	-2.0, 10.0	114.0, 139.0	-19.5, 10.5	107.0, 115.0	-13.0, -3.0	107.0, 131.0	-13.0, 2.0
Min, Max	102, 154	-2, 10	100, 147	-25, 24	103, 147	-19, 4	100, 154	-25, 24

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	122.7	-0.7	137.8	6.8	115.0	-9.3	123.8	-2.4
SD	23.63	26.16	17.67	12.15	20.36	13.37	21.16	16.68
Median	131.0	-4.0	143.5	4.5	110.0	-7.0	120.0	-4.0
Q1, Q3	96.0, 141.0	-25.0, 27.0	127.0, 148.5	-3.0, 16.5	106.0, 120.0	-14.0, 0.0	107.0, 142.0	-9.0, 5.0
Min, Max	96, 141	-25, 27	112, 152	-4, 22	92, 152	-33, 5	92, 152	-33, 27
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	8	8	14	14
Mean	151.0	16.0	130.8	-0.3	127.8	2.8	131.9	3.8
SD	21.21	8.49	10.24	20.90	16.29	9.98	16.40	13.73
Median	151.0	16.0	131.0	5.0	128.0	0.5	131.0	5.0
Q1, Q3	136.0, 166.0	10.0, 22.0	122.5, 139.0	-12.5, 12.0	124.0, 133.5	-4.5, 10.0	124.0, 136.0	-3.0, 12.0
Min, Max	136, 166	10, 22	119, 142	-30, 19	96, 155	-10, 20	96, 166	-30, 22

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 3 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	124.0	10.0	127.0	-4.0	131.8	2.0	129.1	0.4
SD	NC	NC	4.55	13.98	14.02	14.40	10.16	13.33
Median	124.0	10.0	127.5	0.5	130.0	3.0	127.5	3.5
Q1, Q3	124.0, 124.0	10.0, 10.0	124.0, 130.0	-13.5, 5.5	121.0, 135.0	-6.0, 15.0	121.0, 132.0	-6.0, 10.0
Min, Max	124, 124	10, 10	121, 132	-24, 7	119, 154	-18, 16	119, 154	-24, 16
Cycle 5 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	132.0	18.0	126.3	-4.8	139.6	9.8	133.5	4.8
SD	NC	NC	16.94	20.73	13.78	13.20	14.98	17.16
Median	132.0	18.0	127.0	-1.0	135.0	14.0	131.0	10.5
Q1, Q3	132.0, 132.0	18.0, 18.0	114.5, 138.0	-20.5, 11.0	129.0, 143.0	4.0, 17.0	129.0, 143.0	-9.0, 17.0
Min, Max	132, 132	18, 18	105, 146	-32, 15	129, 162	-10, 24	105, 162	-32, 24

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	3	3	5	5	8	8
Mean	NC	NC	130.0	7.3	128.8	-1.0	129.3	2.1
SD	NC	NC	11.36	6.66	11.05	9.27	10.35	8.97
Median	NC	NC	135.0	4.0	123.0	4.0	129.0	4.0
Q1, Q3	NC, NC	NC, NC	117.0, 138.0	3.0, 15.0	121.0, 137.0	-4.0, 5.0	120.0, 137.5	-0.5, 5.5
Min, Max	NC, NC	NC, NC	117, 138	3, 15	119, 144	-16, 6	117, 144	-16, 15
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	146.3	23.7	116.3	-15.7	131.3	4.0
SD	NC	NC	17.24	16.07	19.50	13.05	23.26	25.21
Median	NC	NC	143.0	17.0	116.0	-17.0	133.5	5.0
Q1, Q3	NC, NC	NC, NC	131.0, 165.0	12.0, 42.0	97.0, 136.0	-28.0, -2.0	116.0, 143.0	-17.0, 17.0
Min, Max	NC, NC	NC, NC	131, 165	12, 42	97, 136	-28, -2	97, 165	-28, 42

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	126.3	3.7	136.5	1.0	130.4	2.6
SD	NC	NC	11.59	6.43	23.33	1.41	15.31	4.83
Median	NC	NC	132.0	1.0	136.5	1.0	132.0	1.0
Q1, Q3	NC, NC	NC, NC	113.0, 134.0	-1.0, 11.0	120.0, 153.0	0.0, 2.0	120.0, 134.0	0.0, 2.0
Min, Max	NC, NC	NC, NC	113, 134	-1, 11	120, 153	0, 2	113, 153	-1, 11
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	124.0	10.0	126.5	-9.0	125.7	-2.7
SD	NC	NC	NC	NC	2.12	22.63	2.08	19.40
Median	NC	NC	124.0	10.0	126.5	-9.0	125.0	7.0
Q1, Q3	NC, NC	NC, NC	124.0, 124.0	10.0, 10.0	125.0, 128.0	-25.0, 7.0	124.0, 128.0	-25.0, 10.0
Min, Max	NC, NC	NC, NC	124, 124	10, 10	125, 128	-25, 7	124, 128	-25, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	102.0	-12.0	117.0	-1.0	109.5	-6.5
SD	NC	NC	NC	NC	NC	NC	10.61	7.78
Median	NC	NC	102.0	-12.0	117.0	-1.0	109.5	-6.5
Q1, Q3	NC, NC	NC, NC	102.0, 102.0	-12.0, -12.0	117.0, 117.0	-1.0, -1.0	102.0, 117.0	-12.0, -1.0
Min, Max	NC, NC	NC, NC	102, 102	-12, -12	117, 117	-1, -1	102, 117	-12, -1
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	114.0	0.0	121.0	3.0	117.5	1.5
SD	NC	NC	NC	NC	NC	NC	4.95	2.12
Median	NC	NC	114.0	0.0	121.0	3.0	117.5	1.5
Q1, Q3	NC, NC	NC, NC	114.0, 114.0	0.0, 0.0	121.0, 121.0	3.0, 3.0	114.0, 121.0	0.0, 3.0
Min, Max	NC, NC	NC, NC	114, 114	0, 0	121, 121	3, 3	114, 121	0, 3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	125.0	11.0	124.0	6.0	124.5	8.5
SD	NC	NC	NC	NC	NC	NC	0.71	3.54
Median	NC	NC	125.0	11.0	124.0	6.0	124.5	8.5
Q1, Q3	NC, NC	NC, NC	125.0, 125.0	11.0, 11.0	124.0, 124.0	6.0, 6.0	124.0, 125.0	6.0, 11.0
Min, Max	NC, NC	NC, NC	125, 125	11, 11	124, 124	6, 6	124, 125	6, 11
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	116.0	2.0	NC	NC	116.0	2.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	116.0	2.0	NC	NC	116.0	2.0
Q1, Q3	NC, NC	NC, NC	116.0, 116.0	2.0, 2.0	NC, NC	NC, NC	116.0, 116.0	2.0, 2.0
Min, Max	NC, NC	NC, NC	116, 116	2, 2	NC, NC	NC, NC	116, 116	2, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	115.0	1.0	NC	NC	115.0	1.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	115.0	1.0	NC	NC	115.0	1.0
Q1, Q3	NC, NC	NC, NC	115.0, 115.0	1.0, 1.0	NC, NC	NC, NC	115.0, 115.0	1.0, 1.0
Min, Max	NC, NC	NC, NC	115, 115	1, 1	NC, NC	NC, NC	115, 115	1, 1
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	112.0	-2.0	NC	NC	112.0	-2.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	112.0	-2.0	NC	NC	112.0	-2.0
Q1, Q3	NC, NC	NC, NC	112.0, 112.0	-2.0, -2.0	NC, NC	NC, NC	112.0, 112.0	-2.0, -2.0
Min, Max	NC, NC	NC, NC	112, 112	-2, -2	NC, NC	NC, NC	112, 112	-2, -2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Systolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	134.7	11.3	131.8	0.8	123.5	-7.8	127.9	-1.7
SD	25.11	6.51	15.09	9.39	21.17	19.46	19.70	16.53
Median	132.0	11.0	129.5	-1.0	124.0	0.0	124.0	2.0
Q1, Q3	111.0, 161.0	5.0, 18.0	120.0, 143.5	-6.5, 8.0	106.5, 141.0	-21.0, 4.0	111.0, 151.0	-8.0, 11.0
Min, Max	111, 161	5, 18	117, 151	-8, 13	93, 152	-42, 14	93, 161	-42, 18

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	69.8		78.4		74.6		75.0	
SD	9.78		9.48		8.29		9.05	
Median	67.5		79.0		72.5		76.0	
Q1, Q3	62.5, 77.0		76.0, 82.0		68.0, 79.0		68.0, 80.0	
Min, Max	61, 83		62, 94		65, 92		61, 94	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	71.8	2.0	78.1	-0.3	71.2	-3.4	73.6	-1.3
SD	5.32	10.86	12.19	3.99	7.79	5.64	9.32	6.44
Median	71.5	6.0	78.0	-1.0	72.0	-1.0	72.0	-1.0
Q1, Q3	67.5, 76.0	-4.5, 8.5	70.0, 84.0	-4.0, 4.0	66.0, 78.0	-10.0, 1.0	69.0, 78.0	-6.0, 4.0
Min, Max	66, 78	-14, 10	61, 99	-6, 5	55, 81	-11, 4	55, 99	-14, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	9	9	20	20
Mean	70.3	0.5	75.9	-2.6	77.9	2.2	75.7	0.2
SD	9.22	4.20	12.05	7.63	8.43	6.50	9.88	6.61
Median	71.0	0.0	69.0	1.0	81.0	2.0	75.5	1.0
Q1, Q3	62.5, 78.0	-2.5, 3.5	66.0, 87.0	-10.0, 3.0	74.0, 84.0	-2.0, 4.0	66.5, 82.5	-3.5, 3.5
Min, Max	60, 79	-4, 6	65, 96	-13, 7	65, 90	-7, 13	60, 96	-13, 13
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	65.7	-6.0	74.0	-1.8	73.2	-1.9	72.2	-2.6
SD	8.62	2.65	7.40	3.43	11.61	4.83	9.87	4.22
Median	64.0	-7.0	76.0	-1.5	72.0	-3.0	73.0	-3.0
Q1, Q3	58.0, 75.0	-8.0, -3.0	69.0, 79.0	-4.0, 0.0	66.0, 78.0	-5.0, 2.0	64.0, 78.0	-7.0, 0.0
Min, Max	58, 75	-8, -3	62, 82	-7, 3	60, 97	-9, 5	58, 97	-9, 5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 6, 1 Hour Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	68.3	-3.3	72.0	-3.8	73.8	-0.3	72.3	-2.0
SD	9.87	5.03	9.08	5.78	8.07	4.95	8.39	5.22
Median	73.0	-4.0	70.5	-2.5	72.0	1.0	72.5	-1.0
Q1, Q3	57.0, 75.0	-8.0, 2.0	65.0, 79.0	-10.0, 0.0	68.0, 75.0	-2.0, 4.0	66.0, 75.0	-5.0, 2.0
Min, Max	57, 75	-8, 2	62, 85	-11, 3	63, 90	-11, 5	57, 90	-11, 5
Cycle 1 Day 6, 4 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	69.3	-2.3	74.7	-1.2	68.0	-6.1	70.4	-3.8
SD	10.69	5.69	8.89	5.42	11.43	5.42	10.39	5.65
Median	75.0	-4.0	76.5	1.5	69.0	-5.0	71.0	-3.5
Q1, Q3	57.0, 76.0	-7.0, 4.0	65.0, 82.0	-4.0, 2.0	56.0, 76.0	-11.0, -1.0	64.0, 80.0	-7.0, 1.0
Min, Max	57, 76	-7, 4	64, 84	-11, 3	52, 85	-14, 0	52, 85	-14, 4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	7	7	14	14
Mean	69.0	-2.7	77.3	-2.0	64.3	-9.1	69.0	-5.7
SD	4.58	6.51	1.71	2.00	21.73	23.61	15.96	16.66
Median	68.0	-3.0	77.5	-1.0	70.0	-2.0	72.0	-1.5
Q1, Q3	65.0, 74.0	-9.0, 4.0	76.0, 78.5	-3.0, -1.0	66.0, 72.0	-7.0, 3.0	68.0, 77.0	-5.0, 2.0
Min, Max	65, 74	-9, 4	75, 79	-5, -1	17, 85	-62, 4	17, 85	-62, 4
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	68.0	-3.7	75.5	-3.8	68.2	-4.0	70.4	-3.8
SD	7.21	8.33	8.19	6.70	6.55	8.00	7.48	7.03
Median	70.0	-1.0	76.0	-4.5	70.5	-4.0	72.0	-3.0
Q1, Q3	60.0, 74.0	-13.0, 3.0	70.5, 80.5	-8.5, 1.0	64.0, 73.0	-10.0, 4.0	65.0, 74.0	-10.0, 3.0
Min, Max	60, 74	-13, 3	65, 85	-11, 5	57, 74	-15, 5	57, 85	-15, 5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	68.0	-3.7	80.3	1.0	68.3	-3.8	71.9	-2.3
SD	11.53	11.06	7.14	5.72	13.43	9.11	11.98	8.27
Median	69.0	-5.0	82.5	1.5	68.5	-4.5	71.0	-4.0
Q1, Q3	56.0, 79.0	-14.0, 8.0	75.5, 85.0	-3.5, 5.5	56.0, 74.0	-12.0, 1.0	66.0, 81.0	-6.0, 4.0
Min, Max	56, 79	-14, 8	70, 86	-6, 7	53, 90	-14, 11	53, 90	-14, 11
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	8	8	14	14
Mean	69.0	-8.0	75.0	-4.3	77.3	2.1	75.4	-1.1
SD	5.66	14.14	3.56	3.77	12.63	12.16	9.99	10.73
Median	69.0	-8.0	74.0	-5.5	77.0	1.0	74.5	-4.0
Q1, Q3	65.0, 73.0	-18.0, 2.0	72.5, 77.5	-7.0, -1.5	73.0, 86.0	-7.5, 14.5	72.0, 80.0	-7.0, 6.0
Min, Max	65, 73	-18, 2	72, 80	-7, 1	52, 94	-15, 16	52, 94	-18, 16

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	64.0	-7.0	76.5	-2.8	74.2	1.6	74.1	-1.0
SD	NC	NC	3.11	5.25	7.12	2.61	6.30	4.62
Median	64.0	-7.0	77.5	-1.5	74.0	2.0	75.5	0.0
Q1, Q3	64.0, 64.0	-7.0, -7.0	74.5, 78.5	-6.5, 1.0	70.0, 79.0	0.0, 4.0	70.0, 79.0	-3.0, 2.0
Min, Max	64, 64	-7, -7	72, 79	-10, 2	65, 83	-2, 4	64, 83	-10, 4
Cycle 5 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	75.0	4.0	74.8	-4.5	74.6	2.0	74.7	-0.4
SD	NC	NC	7.23	7.23	9.40	6.04	7.53	6.82
Median	75.0	4.0	75.0	-3.5	76.0	-1.0	75.5	0.0
Q1, Q3	75.0, 75.0	4.0, 4.0	68.5, 81.0	-10.5, 1.5	69.0, 77.0	-2.0, 8.0	69.0, 81.0	-4.0, 4.0
Min, Max	75, 75	4, 4	68, 81	-13, 2	63, 88	-4, 9	63, 88	-13, 9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	3	3	5	5	8	8
Mean	NC	NC	78.3	0.0	74.8	2.2	76.1	1.4
SD	NC	NC	11.24	9.54	10.35	3.70	10.03	5.93
Median	NC	NC	81.0	1.0	68.0	1.0	74.5	1.0
Q1, Q3	NC, NC	NC, NC	66.0, 88.0	-10.0, 9.0	68.0, 84.0	0.0, 5.0	67.0, 86.0	-1.0, 6.0
Min, Max	NC, NC	NC, NC	66, 88	-10, 9	66, 88	-2, 7	66, 88	-10, 9
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	84.7	6.3	60.7	-7.0	72.7	-0.3
SD	NC	NC	9.71	7.64	1.53	1.00	14.54	8.78
Median	NC	NC	87.0	8.0	61.0	-7.0	68.0	-4.0
Q1, Q3	NC, NC	NC, NC	74.0, 93.0	-2.0, 13.0	59.0, 62.0	-8.0, -6.0	61.0, 87.0	-7.0, 8.0
Min, Max	NC, NC	NC, NC	74, 93	-2, 13	59, 62	-8, -6	59, 93	-8, 13

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	79.3	1.0	59.5	-8.0	71.4	-2.6
SD	NC	NC	5.51	3.46	7.78	4.24	12.18	5.90
Median	NC	NC	82.0	3.0	59.5	-8.0	73.0	-3.0
Q1, Q3	NC, NC	NC, NC	73.0, 83.0	-3.0, 3.0	54.0, 65.0	-11.0, -5.0	65.0, 82.0	-5.0, 3.0
Min, Max	NC, NC	NC, NC	73, 83	-3, 3	54, 65	-11, -5	54, 83	-11, 3
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	72.0	-4.0	64.0	-3.5	66.7	-3.7
SD	NC	NC	NC	NC	5.66	2.12	6.11	1.53
Median	NC	NC	72.0	-4.0	64.0	-3.5	68.0	-4.0
Q1, Q3	NC, NC	NC, NC	72.0, 72.0	-4.0, -4.0	60.0, 68.0	-5.0, -2.0	60.0, 72.0	-5.0, -2.0
Min, Max	NC, NC	NC, NC	72, 72	-4, -4	60, 68	-5, -2	60, 72	-5, -2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	69.0	-7.0	78.0	8.0	73.5	0.5
SD	NC	NC	NC	NC	NC	NC	6.36	10.61
Median	NC	NC	69.0	-7.0	78.0	8.0	73.5	0.5
Q1, Q3	NC, NC	NC, NC	69.0, 69.0	-7.0, -7.0	78.0, 78.0	8.0, 8.0	69.0, 78.0	-7.0, 8.0
Min, Max	NC, NC	NC, NC	69, 69	-7, -7	78, 78	8, 8	69, 78	-7, 8
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	68.0	-8.0	85.0	15.0	76.5	3.5
SD	NC	NC	NC	NC	NC	NC	12.02	16.26
Median	NC	NC	68.0	-8.0	85.0	15.0	76.5	3.5
Q1, Q3	NC, NC	NC, NC	68.0, 68.0	-8.0, -8.0	85.0, 85.0	15.0, 15.0	68.0, 85.0	-8.0, 15.0
Min, Max	NC, NC	NC, NC	68, 68	-8, -8	85, 85	15, 15	68, 85	-8, 15

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	85.0	9.0	78.0	8.0	81.5	8.5
SD	NC	NC	NC	NC	NC	NC	4.95	0.71
Median	NC	NC	85.0	9.0	78.0	8.0	81.5	8.5
Q1, Q3	NC, NC	NC, NC	85.0, 85.0	9.0, 9.0	78.0, 78.0	8.0, 8.0	78.0, 85.0	8.0, 9.0
Min, Max	NC, NC	NC, NC	85, 85	9, 9	78, 78	8, 8	78, 85	8, 9
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	80.0	4.0	NC	NC	80.0	4.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	80.0	4.0	NC	NC	80.0	4.0
Q1, Q3	NC, NC	NC, NC	80.0, 80.0	4.0, 4.0	NC, NC	NC, NC	80.0, 80.0	4.0, 4.0
Min, Max	NC, NC	NC, NC	80, 80	4, 4	NC, NC	NC, NC	80, 80	4, 4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	75.0	-1.0	NC	NC	75.0	-1.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	75.0	-1.0	NC	NC	75.0	-1.0
Q1, Q3	NC, NC	NC, NC	75.0, 75.0	-1.0, -1.0	NC, NC	NC, NC	75.0, 75.0	-1.0, -1.0
Min, Max	NC, NC	NC, NC	75, 75	-1, -1	NC, NC	NC, NC	75, 75	-1, -1
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	75.0	-1.0	NC	NC	75.0	-1.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	75.0	-1.0	NC	NC	75.0	-1.0
Q1, Q3	NC, NC	NC, NC	75.0, 75.0	-1.0, -1.0	NC, NC	NC, NC	75.0, 75.0	-1.0, -1.0
Min, Max	NC, NC	NC, NC	75, 75	-1, -1	NC, NC	NC, NC	75, 75	-1, -1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Diastolic Blood Pressure (mmHg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	77.7	6.0	79.8	0.5	71.6	-2.4	75.0	0.1
SD	8.33	3.46	3.86	4.04	14.91	7.52	11.78	6.67
Median	75.0	4.0	79.5	1.5	73.0	-2.0	76.0	1.0
Q1, Q3	71.0, 87.0	4.0, 10.0	76.5, 83.0	-2.5, 3.5	59.5, 79.5	-8.0, 3.5	71.0, 82.0	-5.0, 4.0
Min, Max	71, 87	4, 10	76, 84	-5, 4	51, 98	-14, 8	51, 98	-14, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	78.5		87.3		82.3		83.2	
SD	18.12		22.86		15.01		17.84	
Median	75.5		78.0		85.5		79.0	
Q1, Q3	66.0, 91.0		71.0, 114.0		75.0, 94.0		71.0, 94.0	
Min, Max	60, 103		68, 125		53, 102		53, 125	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	80.8	2.3	76.4	-10.9	78.8	-3.5	78.4	-4.9
SD	24.07	9.43	17.90	12.90	14.36	6.40	16.68	10.26
Median	75.5	3.5	75.0	-12.0	77.0	-3.5	76.0	-8.0
Q1, Q3	64.0, 97.5	-5.5, 10.0	58.0, 93.0	-21.0, -8.0	72.0, 90.0	-9.0, 0.0	63.0, 92.0	-10.0, 0.0
Min, Max	58, 114	-9, 11	56, 98	-27, 14	54, 102	-11, 10	54, 114	-27, 14

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4	Change from baseline	N=7	Change from baseline	N=10	Change from baseline	Value	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	9	9	20	20
Mean	79.5	1.0	79.1	-8.1	84.4	-1.1	81.6	-3.2
SD	21.14	6.68	15.45	11.54	12.96	3.79	14.96	8.36
Median	77.5	0.0	78.0	-6.0	88.0	-1.0	84.0	-2.0
Q1, Q3	65.0, 94.0	-4.5, 6.5	63.0, 97.0	-17.0, -3.0	79.0, 93.0	-1.0, 0.0	71.0, 93.0	-6.5, 1.5
Min, Max	56, 107	-5, 9	62, 98	-27, 10	57, 101	-7, 4	56, 107	-27, 10
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	81.7	-3.0	79.5	-1.5	83.6	0.9	81.9	-0.6
SD	22.85	7.21	20.83	10.25	14.38	5.46	17.03	7.32
Median	70.0	-5.0	72.5	-3.5	83.0	0.0	81.5	-1.5
Q1, Q3	67.0, 108.0	-9.0, 5.0	63.0, 96.0	-8.0, -1.0	81.0, 92.0	-2.0, 6.0	67.0, 96.0	-5.0, 5.0
Min, Max	67, 108	-9, 5	60, 113	-11, 18	60, 103	-7, 9	60, 113	-11, 18

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4	Change from baseline	N=7	Change from baseline	N=10	Change from baseline	Value	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 6,								
1 Hour Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	78.0	-6.7	78.3	-2.7	81.4	-0.7	79.8	-2.3
SD	21.17	8.96	21.22	11.69	14.28	5.83	16.85	8.39
Median	70.0	-2.0	70.0	-5.0	82.0	0.0	75.5	-3.5
Q1, Q3	62.0, 102.0	-17.0, -1.0	62.0, 98.0	-11.0, -3.0	72.0, 89.0	-5.0, 3.0	64.0, 96.0	-7.0, 2.0
Min, Max	62, 102	-17, -1	59, 111	-12, 20	61, 104	-8, 8	59, 111	-17, 20
Cycle 1 Day 6,								
4 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	85.7	1.0	78.8	-2.2	82.1	0.0	81.6	-0.6
SD	22.03	6.24	16.59	13.76	15.09	8.28	15.84	9.70
Median	75.0	-1.0	76.0	-6.5	81.0	1.0	76.5	-2.5
Q1, Q3	71.0, 111.0	-4.0, 8.0	65.0, 98.0	-12.0, 7.0	73.0, 89.0	-6.0, 6.0	71.0, 98.0	-6.0, 7.0
Min, Max	71, 111	-4, 8	59, 99	-16, 21	60, 107	-14, 12	59, 111	-16, 21

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	7	7	14	14
Mean	87.3	2.7	62.8	-10.8	84.7	1.7	79.0	-1.6
SD	30.01	14.01	3.59	5.91	13.25	5.82	18.37	9.48
Median	81.0	2.0	63.5	-9.5	86.0	2.0	76.0	-1.0
Q1, Q3	61.0, 120.0	-11.0, 17.0	60.0, 65.5	-14.5, -7.0	71.0, 99.0	-3.0, 7.0	65.0, 87.0	-9.0, 4.0
Min, Max	61, 120	-11, 17	58, 66	-19, -5	65, 101	-8, 9	58, 120	-19, 17
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	83.7	-1.0	62.5	-11.0	81.3	-4.8	76.1	-5.8
SD	21.36	5.20	3.87	6.22	11.38	6.94	14.95	7.03
Median	75.0	-4.0	63.5	-11.0	82.5	-2.0	73.0	-4.0
Q1, Q3	68.0, 108.0	-4.0, 5.0	60.0, 65.0	-16.0, -6.0	73.0, 92.0	-12.0, 0.0	64.0, 83.0	-12.0, -2.0
Min, Max	68, 108	-4, 5	57, 66	-18, -4	64, 94	-15, 2	57, 108	-18, 5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	87.3	2.7	70.0	-3.5	81.0	-5.2	79.1	-2.8
SD	17.04	3.21	10.65	13.48	7.87	3.87	12.20	7.99
Median	78.0	4.0	70.0	-7.5	81.0	-5.0	78.0	-4.0
Q1, Q3	77.0, 107.0	-1.0, 5.0	63.0, 77.0	-13.5, 6.5	75.0, 89.0	-5.0, -4.0	71.0, 83.0	-5.0, 0.0
Min, Max	77, 107	-1, 5	57, 83	-14, 15	70, 90	-12, 0	57, 107	-14, 15
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	8	8	14	14
Mean	82.0	6.5	73.8	0.3	79.1	-1.1	78.0	0.4
SD	12.73	7.78	11.09	16.42	12.31	6.06	11.46	9.68
Median	82.0	6.5	71.5	-0.5	82.0	-2.0	78.5	-1.5
Q1, Q3	73.0, 91.0	1.0, 12.0	65.0, 82.5	-12.5, 13.0	71.0, 88.0	-6.0, 1.5	66.0, 88.0	-6.0, 6.0
Min, Max	73, 91	1, 12	64, 88	-18, 20	58, 93	-7, 11	58, 93	-18, 20

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	83.0	4.0	71.3	-2.3	75.4	1.4	74.5	0.2
SD	NC	NC	2.63	6.95	7.02	13.89	6.11	10.34
Median	83.0	4.0	71.0	-2.0	74.0	-7.0	73.5	-2.0
Q1, Q3	83.0, 83.0	4.0, 4.0	69.0, 73.5	-6.5, 2.0	73.0, 75.0	-7.0, 11.0	69.0, 75.0	-7.0, 6.0
Min, Max	83, 83	4, 4	69, 74	-11, 6	68, 87	-11, 21	68, 87	-11, 21
Cycle 5 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	83.0	4.0	73.0	-0.5	74.6	0.6	74.8	0.5
SD	NC	NC	11.34	13.87	12.24	8.26	10.88	9.81
Median	83.0	4.0	71.0	-6.5	80.0	-3.0	77.5	-3.5
Q1, Q3	83.0, 83.0	4.0, 4.0	64.5, 81.5	-9.0, 8.0	66.0, 81.0	-6.0, 5.0	66.0, 83.0	-6.0, 5.0
Min, Max	83, 83	4, 4	62, 88	-9, 20	58, 88	-6, 13	58, 88	-9, 20

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	3	3	5	5	8	8
Mean	NC	NC	74.7	0.3	84.6	10.6	80.9	6.8
SD	NC	NC	7.64	13.32	14.59	9.91	12.83	11.62
Median	NC	NC	73.0	-3.0	80.0	11.0	78.0	9.5
Q1, Q3	NC, NC	NC, NC	68.0, 83.0	-11.0, 15.0	76.0, 86.0	8.0, 15.0	72.5, 84.5	-3.5, 15.0
Min, Max	NC, NC	NC, NC	68, 83	-11, 15	72, 109	-4, 23	68, 109	-11, 23
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	68.3	-6.0	79.0	5.0	73.7	-0.5
SD	NC	NC	2.31	6.24	19.70	4.58	13.84	7.77
Median	NC	NC	67.0	-4.0	85.0	4.0	69.0	0.0
Q1, Q3	NC, NC	NC, NC	67.0, 71.0	-13.0, -1.0	57.0, 95.0	1.0, 10.0	67.0, 85.0	-4.0, 4.0
Min, Max	NC, NC	NC, NC	67, 71	-13, -1	57, 95	1, 10	57, 95	-13, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	75.7	1.3	66.0	2.0	71.8	1.6
SD	NC	NC	9.50	13.65	9.90	5.66	9.88	10.06
Median	NC	NC	76.0	-5.0	66.0	2.0	73.0	-2.0
Q1, Q3	NC, NC	NC, NC	66.0, 85.0	-8.0, 17.0	59.0, 73.0	-2.0, 6.0	66.0, 76.0	-5.0, 6.0
Min, Max	NC, NC	NC, NC	66, 85	-8, 17	59, 73	-2, 6	59, 85	-8, 17
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	85.0	17.0	64.0	0.0	71.0	5.7
SD	NC	NC	NC	NC	9.90	5.66	14.00	10.60
Median	NC	NC	85.0	17.0	64.0	0.0	71.0	4.0
Q1, Q3	NC, NC	NC, NC	85.0, 85.0	17.0, 17.0	57.0, 71.0	-4.0, 4.0	57.0, 85.0	-4.0, 17.0
Min, Max	NC, NC	NC, NC	85, 85	17, 17	57, 71	-4, 4	57, 85	-4, 17

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	88.0	20.0	87.0	12.0	87.5	16.0
SD	NC	NC	NC	NC	NC	NC	0.71	5.66
Median	NC	NC	88.0	20.0	87.0	12.0	87.5	16.0
Q1, Q3	NC, NC	NC, NC	88.0, 88.0	20.0, 20.0	87.0, 87.0	12.0, 12.0	87.0, 88.0	12.0, 20.0
Min, Max	NC, NC	NC, NC	88, 88	20, 20	87, 87	12, 12	87, 88	12, 20
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	81.0	13.0	92.0	17.0	86.5	15.0
SD	NC	NC	NC	NC	NC	NC	7.78	2.83
Median	NC	NC	81.0	13.0	92.0	17.0	86.5	15.0
Q1, Q3	NC, NC	NC, NC	81.0, 81.0	13.0, 13.0	92.0, 92.0	17.0, 17.0	81.0, 92.0	13.0, 17.0
Min, Max	NC, NC	NC, NC	81, 81	13, 13	92, 92	17, 17	81, 92	13, 17

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	104.0	36.0	80.0	5.0	92.0	20.5
SD	NC	NC	NC	NC	NC	NC	16.97	21.92
Median	NC	NC	104.0	36.0	80.0	5.0	92.0	20.5
Q1, Q3	NC, NC	NC, NC	104.0, 104.0	36.0, 36.0	80.0, 80.0	5.0, 5.0	80.0, 104.0	5.0, 36.0
Min, Max	NC, NC	NC, NC	104, 104	36, 36	80, 80	5, 5	80, 104	5, 36
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	91.0	23.0	NC	NC	91.0	23.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	91.0	23.0	NC	NC	91.0	23.0
Q1, Q3	NC, NC	NC, NC	91.0, 91.0	23.0, 23.0	NC, NC	NC, NC	91.0, 91.0	23.0, 23.0
Min, Max	NC, NC	NC, NC	91, 91	23, 23	NC, NC	NC, NC	91, 91	23, 23

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	95.0	27.0	NC	NC	95.0	27.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	95.0	27.0	NC	NC	95.0	27.0
Q1, Q3	NC, NC	NC, NC	95.0, 95.0	27.0, 27.0	NC, NC	NC, NC	95.0, 95.0	27.0, 27.0
Min, Max	NC, NC	NC, NC	95, 95	27, 27	NC, NC	NC, NC	95, 95	27, 27
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	86.0	18.0	NC	NC	86.0	18.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	86.0	18.0	NC	NC	86.0	18.0
Q1, Q3	NC, NC	NC, NC	86.0, 86.0	18.0, 18.0	NC, NC	NC, NC	86.0, 86.0	18.0, 18.0
Min, Max	NC, NC	NC, NC	86, 86	18, 18	NC, NC	NC, NC	86, 86	18, 18

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Pulse Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	121.3	36.7	72.5	-1.0	73.9	-5.0	83.0	4.4
SD	39.02	45.79	11.21	9.59	11.68	9.35	26.58	25.39
Median	120.0	17.0	72.5	-3.0	75.5	-1.0	80.0	0.0
Q1, Q3	83.0, 161.0	4.0, 89.0	63.0, 82.0	-8.0, 6.0	67.0, 82.0	-11.0, 1.0	65.0, 84.0	-9.0, 5.0
Min, Max	83, 161	4, 89	61, 84	-10, 12	53, 89	-23, 5	53, 161	-23, 89

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	17.5		17.4		18.7		18.0	
SD	1.00		1.13		2.31		1.83	
Median	18.0		18.0		18.0		18.0	
Q1, Q3	17.0, 18.0		16.0, 18.0		18.0, 20.0		17.0, 18.0	
Min, Max	16, 18		16, 19		16, 24		16, 24	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	17.0	-0.5	19.1	1.7	19.0	0.3	18.7	0.6
SD	1.15	1.00	4.02	3.73	3.33	2.16	3.28	2.67
Median	17.0	0.0	18.0	0.0	18.0	0.0	18.0	0.0
Q1, Q3	16.0, 18.0	-1.0, 0.0	17.0, 19.0	0.0, 2.0	18.0, 18.0	-1.0, 0.0	17.0, 18.0	0.0, 0.0
Min, Max	16, 18	-2, 0	16, 28	0, 10	15, 26	-2, 6	15, 28	-2, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	9	9	20	20
Mean	17.0	-0.5	18.0	0.6	19.1	0.6	18.3	0.4
SD	1.15	1.00	1.29	0.98	3.02	1.51	2.30	1.27
Median	17.0	0.0	18.0	0.0	18.0	0.0	18.0	0.0
Q1, Q3	16.0, 18.0	-1.0, 0.0	17.0, 19.0	0.0, 2.0	18.0, 20.0	0.0, 0.0	16.5, 18.5	0.0, 0.0
Min, Max	16, 18	-2, 0	16, 20	0, 2	16, 24	-1, 4	16, 24	-2, 4
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	18.0	0.0	17.7	0.3	18.3	-0.4	18.1	-0.1
SD	2.00	2.00	0.82	1.37	2.24	1.01	1.76	1.28
Median	18.0	0.0	18.0	0.0	18.0	0.0	18.0	0.0
Q1, Q3	16.0, 20.0	-2.0, 2.0	18.0, 18.0	-1.0, 2.0	18.0, 18.0	-1.0, 0.0	18.0, 18.0	-1.0, 0.0
Min, Max	16, 20	-2, 2	16, 18	-1, 2	16, 24	-2, 1	16, 24	-2, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4	Change from baseline	N=7	Change from baseline	N=10	Change from baseline	Value	Change from baseline
	Value		Value		Value		Value	
Cycle 1 Day 6,								
1 Hour Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	17.3	-0.7	17.7	0.3	18.6	-0.4	18.1	-0.2
SD	1.15	1.15	0.82	1.37	2.07	1.01	1.63	1.17
Median	18.0	0.0	18.0	0.0	18.0	0.0	18.0	0.0
Q1, Q3	16.0, 18.0	-2.0, 0.0	18.0, 18.0	-1.0, 2.0	18.0, 18.0	-1.0, 0.0	18.0, 18.0	-1.0, 0.0
Min, Max	16, 18	-2, 0	16, 18	-1, 2	17, 24	-2, 1	16, 24	-2, 2
Cycle 1 Day 6,								
4 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	17.7	-0.3	17.7	0.3	18.3	-0.7	18.0	-0.3
SD	0.58	0.58	0.82	1.37	2.24	1.12	1.64	1.18
Median	18.0	0.0	18.0	0.0	18.0	0.0	18.0	0.0
Q1, Q3	17.0, 18.0	-1.0, 0.0	18.0, 18.0	-1.0, 2.0	18.0, 18.0	-2.0, 0.0	18.0, 18.0	-1.0, 0.0
Min, Max	17, 18	-1, 0	16, 18	-1, 2	16, 24	-2, 1	16, 24	-2, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	7	7	14	14
Mean	18.0	0.0	18.0	0.5	17.4	-1.3	17.7	-0.5
SD	0.00	0.00	1.83	0.58	0.98	2.21	1.14	1.74
Median	18.0	0.0	18.0	0.5	18.0	0.0	18.0	0.0
Q1, Q3	18.0, 18.0	0.0, 0.0	16.5, 19.5	0.0, 1.0	16.0, 18.0	-2.0, 0.0	17.0, 18.0	0.0, 0.0
Min, Max	18, 18	0, 0	16, 20	0, 1	16, 18	-6, 0	16, 20	-6, 1
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	18.0	0.0	17.3	-0.3	18.7	-0.2	18.1	-0.2
SD	0.00	0.00	1.50	0.96	2.73	0.41	2.02	0.55
Median	18.0	0.0	17.0	-0.5	18.0	0.0	18.0	0.0
Q1, Q3	18.0, 18.0	0.0, 0.0	16.0, 18.5	-1.0, 0.5	18.0, 18.0	0.0, 0.0	18.0, 18.0	0.0, 0.0
Min, Max	18, 18	0, 0	16, 19	-1, 1	16, 24	-1, 0	16, 24	-1, 1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	17.3	-0.7	17.3	-0.3	18.8	0.0	18.0	-0.2
SD	1.15	1.15	1.50	0.96	2.56	0.63	2.04	0.83
Median	18.0	0.0	17.0	-0.5	18.0	0.0	18.0	0.0
Q1, Q3	16.0, 18.0	-2.0, 0.0	16.0, 18.5	-1.0, 0.5	18.0, 18.0	0.0, 0.0	17.0, 18.0	-1.0, 0.0
Min, Max	16, 18	-2, 0	16, 19	-1, 1	17, 24	-1, 1	16, 24	-2, 1
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	8	8	14	14
Mean	18.0	0.0	17.8	0.3	16.9	-1.8	17.3	-0.9
SD	0.00	0.00	1.71	2.06	1.46	2.19	1.44	2.13
Median	18.0	0.0	17.5	0.0	17.5	-2.0	18.0	0.0
Q1, Q3	18.0, 18.0	0.0, 0.0	16.5, 19.0	-1.0, 1.5	16.0, 18.0	-2.5, 0.0	16.0, 18.0	-2.0, 0.0
Min, Max	18, 18	0, 0	16, 20	-2, 3	14, 18	-6, 1	14, 20	-6, 3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	18.0	0.0	17.3	-0.3	17.8	-1.4	17.6	-0.8
SD	NC	NC	0.96	2.06	1.48	3.97	1.17	2.97
Median	18.0	0.0	17.5	0.0	18.0	0.0	18.0	0.0
Q1, Q3	18.0, 18.0	0.0, 0.0	16.5, 18.0	-1.5, 1.0	17.0, 18.0	-2.0, 1.0	17.0, 18.0	-2.0, 1.0
Min, Max	18, 18	0, 0	16, 18	-3, 2	16, 20	-8, 2	16, 20	-8, 2
Cycle 5 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	18.0	0.0	17.0	-0.5	18.0	-1.2	17.6	-0.8
SD	NC	NC	1.15	1.29	1.41	2.68	1.26	1.99
Median	18.0	0.0	17.0	-0.5	18.0	0.0	18.0	0.0
Q1, Q3	18.0, 18.0	0.0, 0.0	16.0, 18.0	-1.5, 0.5	18.0, 18.0	0.0, 0.0	16.0, 18.0	-1.0, 0.0
Min, Max	18, 18	0, 0	16, 18	-2, 1	16, 20	-6, 0	16, 20	-6, 1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	3	3	5	5	8	8
Mean	NC	NC	17.3	-0.3	16.6	-2.6	16.9	-1.8
SD	NC	NC	1.15	0.58	0.89	3.58	0.99	2.96
Median	NC	NC	18.0	0.0	16.0	-2.0	16.5	-0.5
Q1, Q3	NC, NC	NC, NC	16.0, 18.0	-1.0, 0.0	16.0, 17.0	-4.0, 0.0	16.0, 18.0	-3.0, 0.0
Min, Max	NC, NC	NC, NC	16, 18	-1, 0	16, 18	-8, 1	16, 18	-8, 1
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	18.3	0.7	17.3	-3.3	17.8	-1.3
SD	NC	NC	0.58	1.53	1.15	3.06	0.98	3.08
Median	NC	NC	18.0	1.0	18.0	-4.0	18.0	-0.5
Q1, Q3	NC, NC	NC, NC	18.0, 19.0	-1.0, 2.0	16.0, 18.0	-6.0, 0.0	18.0, 18.0	-4.0, 1.0
Min, Max	NC, NC	NC, NC	18, 19	-1, 2	16, 18	-6, 0	16, 19	-6, 2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	17.3	-0.3	17.0	-2.0	17.2	-1.0
SD	NC	NC	1.15	0.58	1.41	0.00	1.10	1.00
Median	NC	NC	18.0	0.0	17.0	-2.0	18.0	-1.0
Q1, Q3	NC, NC	NC, NC	16.0, 18.0	-1.0, 0.0	16.0, 18.0	-2.0, -2.0	16.0, 18.0	-2.0, 0.0
Min, Max	NC, NC	NC, NC	16, 18	-1, 0	16, 18	-2, -2	16, 18	-2, 0
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	18.0	-1.0	17.0	-2.0	17.3	-1.7
SD	NC	NC	NC	NC	1.41	2.83	1.15	2.08
Median	NC	NC	18.0	-1.0	17.0	-2.0	18.0	-1.0
Q1, Q3	NC, NC	NC, NC	18.0, 18.0	-1.0, -1.0	16.0, 18.0	-4.0, 0.0	16.0, 18.0	-4.0, 0.0
Min, Max	NC, NC	NC, NC	18, 18	-1, -1	16, 18	-4, 0	16, 18	-4, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	18.0	-1.0	16.0	-2.0	17.0	-1.5
SD	NC	NC	NC	NC	NC	NC	1.41	0.71
Median	NC	NC	18.0	-1.0	16.0	-2.0	17.0	-1.5
Q1, Q3	NC, NC	NC, NC	18.0, 18.0	-1.0, -1.0	16.0, 16.0	-2.0, -2.0	16.0, 18.0	-2.0, -1.0
Min, Max	NC, NC	NC, NC	18, 18	-1, -1	16, 16	-2, -2	16, 18	-2, -1
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	16.0	-3.0	18.0	0.0	17.0	-1.5
SD	NC	NC	NC	NC	NC	NC	1.41	2.12
Median	NC	NC	16.0	-3.0	18.0	0.0	17.0	-1.5
Q1, Q3	NC, NC	NC, NC	16.0, 16.0	-3.0, -3.0	18.0, 18.0	0.0, 0.0	16.0, 18.0	-3.0, 0.0
Min, Max	NC, NC	NC, NC	16, 16	-3, -3	18, 18	0, 0	16, 18	-3, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	18.0	-1.0	18.0	0.0	18.0	-0.5
SD	NC	NC	NC	NC	NC	NC	0.00	0.71
Median	NC	NC	18.0	-1.0	18.0	0.0	18.0	-0.5
Q1, Q3	NC, NC	NC, NC	18.0, 18.0	-1.0, -1.0	18.0, 18.0	0.0, 0.0	18.0, 18.0	-1.0, 0.0
Min, Max	NC, NC	NC, NC	18, 18	-1, -1	18, 18	0, 0	18, 18	-1, 0
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	16.0	-3.0	NC	NC	16.0	-3.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	16.0	-3.0	NC	NC	16.0	-3.0
Q1, Q3	NC, NC	NC, NC	16.0, 16.0	-3.0, -3.0	NC, NC	NC, NC	16.0, 16.0	-3.0, -3.0
Min, Max	NC, NC	NC, NC	16, 16	-3, -3	NC, NC	NC, NC	16, 16	-3, -3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	16.0	-3.0	NC	NC	16.0	-3.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	16.0	-3.0	NC	NC	16.0	-3.0
Q1, Q3	NC, NC	NC, NC	16.0, 16.0	-3.0, -3.0	NC, NC	NC, NC	16.0, 16.0	-3.0, -3.0
Min, Max	NC, NC	NC, NC	16, 16	-3, -3	NC, NC	NC, NC	16, 16	-3, -3
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	16.0	-3.0	NC	NC	16.0	-3.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	16.0	-3.0	NC	NC	16.0	-3.0
Q1, Q3	NC, NC	NC, NC	16.0, 16.0	-3.0, -3.0	NC, NC	NC, NC	16.0, 16.0	-3.0, -3.0
Min, Max	NC, NC	NC, NC	16, 16	-3, -3	NC, NC	NC, NC	16, 16	-3, -3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Respiratory Rate (breaths/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	40.3	22.3	17.0	-0.5	17.4	-1.1	21.9	3.7
SD	40.43	40.43	1.15	1.29	0.92	2.47	18.04	18.16
Median	18.0	0.0	17.0	-0.5	18.0	-1.0	18.0	0.0
Q1, Q3	16.0, 87.0	-2.0, 69.0	16.0, 18.0	-1.5, 0.5	16.5, 18.0	-2.0, 0.5	16.0, 18.0	-2.0, 1.0
Min, Max	16, 87	-2, 69	16, 18	-2, 1	16, 18	-6, 2	16, 87	-6, 69

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	36.53		36.73		36.67		36.66	
SD	0.386		0.454		0.330		0.372	
Median	36.55		36.50		36.70		36.70	
Q1, Q3	36.20, 36.85		36.40, 37.00		36.40, 36.90		36.40, 36.90	
Min, Max	36.1, 36.9		36.3, 37.6		36.1, 37.1		36.1, 37.6	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	36.70	0.18	36.64	-0.09	36.52	-0.15	36.60	-0.07
SD	0.440	0.171	0.223	0.398	0.447	0.372	0.373	0.360
Median	36.70	0.15	36.60	0.10	36.65	-0.20	36.60	0.00
Q1, Q3	36.35, 37.05	0.05, 0.30	36.50, 36.80	-0.60, 0.20	36.40, 36.70	-0.40, 0.30	36.50, 36.80	-0.40, 0.20
Min, Max	36.2, 37.2	0.0, 0.4	36.3, 37.0	-0.7, 0.3	35.7, 37.1	-0.6, 0.4	35.7, 37.2	-0.7, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	9	9	20	20
Mean	36.85	0.33	36.63	-0.10	36.52	-0.12	36.63	-0.03
SD	0.370	0.556	0.468	0.611	0.429	0.356	0.429	0.502
Median	36.90	0.20	36.80	0.10	36.60	-0.20	36.65	0.05
Q1, Q3	36.55, 37.15	-0.05, 0.70	36.40, 36.90	-0.50, 0.40	36.50, 36.70	-0.40, 0.20	36.45, 36.90	-0.30, 0.30
Min, Max	36.4, 37.2	-0.2, 1.1	35.7, 37.1	-1.3, 0.4	35.6, 37.1	-0.6, 0.4	35.6, 37.2	-1.3, 1.1
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	36.43	-0.17	36.60	-0.08	36.51	-0.22	36.53	-0.17
SD	0.153	0.416	0.245	0.412	0.481	0.338	0.364	0.358
Median	36.40	-0.30	36.70	-0.05	36.70	-0.30	36.65	-0.15
Q1, Q3	36.30, 36.60	-0.50, 0.30	36.40, 36.80	-0.20, 0.20	36.10, 36.80	-0.40, 0.00	36.30, 36.80	-0.40, 0.10
Min, Max	36.3, 36.6	-0.5, 0.3	36.2, 36.8	-0.8, 0.4	35.8, 37.1	-0.9, 0.2	35.8, 37.1	-0.9, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 1 Hour Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	36.33	-0.27	36.70	0.02	36.46	-0.26	36.52	-0.17
SD	0.115	0.321	0.237	0.500	0.480	0.364	0.382	0.407
Median	36.40	-0.40	36.75	0.15	36.60	-0.20	36.60	-0.15
Q1, Q3	36.20, 36.40	-0.50, 0.10	36.60, 36.80	-0.10, 0.30	36.00, 36.90	-0.50, -0.10	36.20, 36.80	-0.50, 0.10
Min, Max	36.2, 36.4	-0.5, 0.1	36.3, 37.0	-0.9, 0.5	35.8, 37.0	-0.9, 0.4	35.8, 37.0	-0.9, 0.5
Cycle 1 Day 6, 4 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	36.63	0.03	36.65	-0.03	36.58	-0.13	36.61	-0.07
SD	0.321	0.473	0.235	0.489	0.466	0.357	0.363	0.401
Median	36.50	0.20	36.75	0.05	36.40	-0.30	36.60	-0.05
Q1, Q3	36.40, 37.00	-0.50, 0.40	36.60, 36.80	-0.20, 0.30	36.40, 36.80	-0.30, 0.00	36.40, 36.80	-0.30, 0.20
Min, Max	36.4, 37.0	-0.5, 0.4	36.2, 36.8	-0.9, 0.5	35.8, 37.3	-0.5, 0.6	35.8, 37.3	-0.9, 0.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	7	7	14	14
Mean	36.57	-0.03	36.65	0.10	36.81	0.14	36.71	0.09
SD	0.058	0.473	0.311	0.258	0.291	0.476	0.271	0.399
Median	36.60	-0.20	36.75	0.10	36.70	0.00	36.65	0.00
Q1, Q3	36.50, 36.60	-0.40, 0.50	36.45, 36.85	-0.10, 0.30	36.60, 37.20	-0.20, 0.40	36.60, 36.90	-0.20, 0.40
Min, Max	36.5, 36.6	-0.4, 0.5	36.2, 36.9	-0.2, 0.4	36.5, 37.2	-0.2, 1.1	36.2, 37.2	-0.4, 1.1
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	36.57	-0.03	36.65	0.10	36.82	0.15	36.71	0.09
SD	0.252	0.551	0.289	0.283	0.248	0.472	0.263	0.411
Median	36.60	0.00	36.65	0.00	36.85	0.20	36.70	0.10
Q1, Q3	36.30, 36.80	-0.60, 0.50	36.45, 36.85	-0.10, 0.30	36.70, 37.00	-0.30, 0.30	36.60, 36.90	-0.10, 0.30
Min, Max	36.3, 36.8	-0.6, 0.5	36.3, 37.0	-0.1, 0.5	36.4, 37.1	-0.4, 0.9	36.3, 37.1	-0.6, 0.9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	36.67	0.07	36.68	0.13	36.75	0.08	36.71	0.09
SD	0.058	0.379	0.330	0.330	0.378	0.527	0.299	0.409
Median	36.70	-0.10	36.65	0.00	36.80	0.05	36.70	-0.10
Q1, Q3	36.60, 36.70	-0.20, 0.50	36.45, 36.90	-0.10, 0.35	36.50, 37.00	-0.40, 0.40	36.60, 37.00	-0.10, 0.40
Min, Max	36.6, 36.7	-0.2, 0.5	36.3, 37.1	-0.1, 0.6	36.2, 37.2	-0.5, 0.9	36.2, 37.2	-0.5, 0.9
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	8	8	14	14
Mean	36.60	-0.25	36.95	0.40	36.33	-0.41	36.54	-0.16
SD	0.283	0.354	0.058	0.216	0.800	0.591	0.657	0.588
Median	36.60	-0.25	36.95	0.45	36.50	-0.25	36.75	-0.10
Q1, Q3	36.40, 36.80	-0.50, 0.00	36.90, 37.00	0.25, 0.55	36.10, 36.80	-0.45, -0.10	36.40, 36.90	-0.40, 0.10
Min, Max	36.4, 36.8	-0.5, 0.0	36.9, 37.0	0.1, 0.6	34.6, 37.2	-1.8, 0.1	34.6, 37.2	-1.8, 0.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	36.80	0.00	36.53	-0.03	36.42	-0.30	36.50	-0.16
SD	NC	NC	0.359	0.330	0.402	0.308	0.359	0.317
Median	36.80	0.00	36.65	0.00	36.50	-0.30	36.65	-0.15
Q1, Q3	36.80, 36.80	0.00, 0.00	36.30, 36.75	-0.30, 0.25	36.00, 36.80	-0.60, -0.10	36.00, 36.80	-0.40, 0.10
Min, Max	36.8, 36.8	0.0, 0.0	36.0, 36.8	-0.4, 0.3	36.0, 36.8	-0.6, 0.1	36.0, 36.8	-0.6, 0.3
Cycle 5 Day 1, Pre-Dose								
Nx	1	1	4	4	5	5	10	10
Mean	36.40	-0.40	36.35	-0.20	36.46	-0.26	36.41	-0.25
SD	NC	NC	0.603	0.535	0.740	0.522	0.606	0.470
Median	36.40	-0.40	36.50	0.05	36.40	-0.50	36.40	-0.20
Q1, Q3	36.40, 36.40	-0.40, -0.40	35.95, 36.75	-0.50, 0.10	35.80, 37.00	-0.60, 0.30	35.80, 36.90	-0.60, 0.10
Min, Max	36.4, 36.4	-0.4, -0.4	35.5, 36.9	-1.0, 0.1	35.7, 37.4	-0.8, 0.3	35.5, 37.4	-1.0, 0.3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	3	3	5	5	8	8
Mean	NC	NC	36.77	0.17	36.38	-0.34	36.53	-0.15
SD	NC	NC	0.115	0.058	0.502	0.297	0.433	0.346
Median	NC	NC	36.70	0.20	36.30	-0.30	36.70	-0.10
Q1, Q3	NC, NC	NC, NC	36.70, 36.90	0.10, 0.20	35.90, 36.90	-0.40, -0.20	36.10, 36.90	-0.35, 0.15
Min, Max	NC, NC	NC, NC	36.7, 36.9	0.1, 0.2	35.9, 36.9	-0.8, 0.0	35.9, 36.9	-0.8, 0.2
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	36.90	0.30	36.87	-0.00	36.88	0.15
SD	NC	NC	0.100	0.100	0.451	0.200	0.293	0.217
Median	NC	NC	36.90	0.30	36.90	0.00	36.90	0.20
Q1, Q3	NC, NC	NC, NC	36.80, 37.00	0.20, 0.40	36.40, 37.30	-0.20, 0.20	36.80, 37.00	0.00, 0.30
Min, Max	NC, NC	NC, NC	36.8, 37.0	0.2, 0.4	36.4, 37.3	-0.2, 0.2	36.4, 37.3	-0.2, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	36.70	0.10	36.90	-0.10	36.78	0.02
SD	NC	NC	0.346	0.300	0.283	0.141	0.303	0.249
Median	NC	NC	36.90	0.10	36.90	-0.10	36.90	0.00
Q1, Q3	NC, NC	NC, NC	36.30, 36.90	-0.20, 0.40	36.70, 37.10	-0.20, 0.00	36.70, 36.90	-0.20, 0.10
Min, Max	NC, NC	NC, NC	36.3, 36.9	-0.2, 0.4	36.7, 37.1	-0.2, 0.0	36.3, 37.1	-0.2, 0.4
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	36.70	-0.10	36.75	-0.25	36.73	-0.20
SD	NC	NC	NC	NC	0.071	0.212	0.058	0.173
Median	NC	NC	36.70	-0.10	36.75	-0.25	36.70	-0.10
Q1, Q3	NC, NC	NC, NC	36.70, 36.70	-0.10, -0.10	36.70, 36.80	-0.40, -0.10	36.70, 36.80	-0.40, -0.10
Min, Max	NC, NC	NC, NC	36.7, 36.7	-0.1, -0.1	36.7, 36.8	-0.4, -0.1	36.7, 36.8	-0.4, -0.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
	Value		Value		Value		Value	
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	36.90	0.10	37.00	-0.10	36.95	0.00
SD	NC	NC	NC	NC	NC	NC	0.071	0.141
Median	NC	NC	36.90	0.10	37.00	-0.10	36.95	0.00
Q1, Q3	NC, NC	NC, NC	36.90, 36.90	0.10, 0.10	37.00, 37.00	-0.10, -0.10	36.90, 37.00	-0.10, 0.10
Min, Max	NC, NC	NC, NC	36.9, 36.9	0.1, 0.1	37.0, 37.0	-0.1, -0.1	36.9, 37.0	-0.1, 0.1
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	37.20	0.40	37.20	0.10	37.20	0.25
SD	NC	NC	NC	NC	NC	NC	0.000	0.212
Median	NC	NC	37.20	0.40	37.20	0.10	37.20	0.25
Q1, Q3	NC, NC	NC, NC	37.20, 37.20	0.40, 0.40	37.20, 37.20	0.10, 0.10	37.20, 37.20	0.10, 0.40
Min, Max	NC, NC	NC, NC	37.2, 37.2	0.4, 0.4	37.2, 37.2	0.1, 0.1	37.2, 37.2	0.1, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	36.80	0.00	36.80	-0.30	36.80	-0.15
SD	NC	NC	NC	NC	NC	NC	0.000	0.212
Median	NC	NC	36.80	0.00	36.80	-0.30	36.80	-0.15
Q1, Q3	NC, NC	NC, NC	36.80, 36.80	0.00, 0.00	36.80, 36.80	-0.30, -0.30	36.80, 36.80	-0.30, 0.00
Min, Max	NC, NC	NC, NC	36.8, 36.8	0.0, 0.0	36.8, 36.8	-0.3, -0.3	36.8, 36.8	-0.3, 0.0
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	36.90	0.10	NC	NC	36.90	0.10
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	36.90	0.10	NC	NC	36.90	0.10
Q1, Q3	NC, NC	NC, NC	36.90, 36.90	0.10, 0.10	NC, NC	NC, NC	36.90, 36.90	0.10, 0.10
Min, Max	NC, NC	NC, NC	36.9, 36.9	0.1, 0.1	NC, NC	NC, NC	36.9, 36.9	0.1, 0.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 23 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	36.90	0.10	NC	NC	36.90	0.10
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	36.90	0.10	NC	NC	36.90	0.10
Q1, Q3	NC, NC	NC, NC	36.90, 36.90	0.10, 0.10	NC, NC	NC, NC	36.90, 36.90	0.10, 0.10
Min, Max	NC, NC	NC, NC	36.9, 36.9	0.1, 0.1	NC, NC	NC, NC	36.9, 36.9	0.1, 0.1
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	37.60	0.80	NC	NC	37.60	0.80
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	37.60	0.80	NC	NC	37.60	0.80
Q1, Q3	NC, NC	NC, NC	37.60, 37.60	0.80, 0.80	NC, NC	NC, NC	37.60, 37.60	0.80, 0.80
Min, Max	NC, NC	NC, NC	37.6, 37.6	0.8, 0.8	NC, NC	NC, NC	37.6, 37.6	0.8, 0.8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Temperature (°C)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
End of Treatment								
Nx	3	3	4	4	8	8	15	15
Mean	36.43	-0.17	36.70	0.15	36.64	0.03	36.61	0.02
SD	0.153	0.586	0.356	0.289	0.526	0.480	0.422	0.441
Median	36.40	-0.40	36.80	0.15	36.75	0.00	36.70	0.10
Q1, Q3	36.30, 36.60	-0.60, 0.50	36.45, 36.95	-0.05, 0.35	36.40, 36.95	-0.25, 0.40	36.30, 36.90	-0.30, 0.50
Min, Max	36.3, 36.6	-0.6, 0.5	36.2, 37.0	-0.2, 0.5	35.6, 37.3	-0.8, 0.7	35.6, 37.3	-0.8, 0.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Weight (kg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4	Change from baseline	N=7	Change from baseline	N=10	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	58.70		78.94		83.85		77.42	
SD	4.419		17.931		19.473		19.016	
Median	57.85		72.20		83.70		72.20	
Q1, Q3	55.55, 61.85		59.90, 98.00		67.00, 100.20		59.90, 98.00	
Min, Max	54.4, 64.7		59.0, 101.3		56.7, 108.9		54.4, 108.9	
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	62.80	0.95	80.18	-0.20	83.16	-0.44	79.40	-0.17
SD	3.536	0.495	17.734	1.042	18.489	1.978	17.576	1.616
Median	62.80	0.95	82.20	-0.35	83.40	-0.10	73.20	-0.10
Q1, Q3	60.30, 65.30	0.60, 1.30	65.95, 94.40	-0.90, 0.50	69.00, 97.85	-1.60, 0.85	65.30, 95.70	-0.50, 1.20
Min, Max	60.3, 65.3	0.6, 1.3	58.5, 97.8	-1.3, 1.2	56.7, 108.1	-3.8, 2.0	56.7, 108.1	-3.8, 2.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Weight (kg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	63.30	-1.40	78.85	-1.53	79.64	-1.06	77.69	-1.28
SD	NC	NC	15.271	3.126	21.083	1.019	17.350	1.942
Median	63.30	-1.40	81.45	-0.80	74.00	-1.30	73.20	-1.35
Q1, Q3	63.30, 63.30	-1.40, -1.40	66.35, 91.35	-3.80, 0.75	67.00, 96.20	-1.80, 0.00	63.30, 92.20	-1.80, 0.00
Min, Max	63.3, 63.3	-1.4, -1.4	60.3, 92.2	-5.8, 1.3	54.9, 106.1	-2.2, 0.0	54.9, 106.1	-5.8, 1.3
Cycle 7 Day 1								
Nx	0	0	3	3	5	5	8	8
Mean	NC	NC	76.70	0.30	79.78	-0.92	78.63	-0.46
SD	NC	NC	20.512	1.058	21.808	1.894	19.863	1.664
Median	NC	NC	73.30	0.70	73.60	-1.70	73.45	-0.10
Q1, Q3	NC, NC	NC, NC	58.10, 98.70	-0.90, 1.10	68.00, 96.60	-1.80, 1.00	63.05, 97.65	-1.75, 1.05
Min, Max	NC, NC	NC, NC	58.1, 98.7	-0.9, 1.1	53.5, 107.2	-3.2, 1.1	53.5, 107.2	-3.2, 1.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Weight (kg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	77.17	0.77	78.90	-0.47	78.03	0.15
SD	NC	NC	21.255	1.419	27.083	2.401	21.795	1.889
Median	NC	NC	72.70	0.50	75.80	0.50	74.25	0.50
Q1, Q3	NC, NC	NC, NC	58.50, 100.30	-0.50, 2.30	53.50, 107.40	-3.20, 1.30	58.50, 100.30	-0.50, 1.30
Min, Max	NC, NC	NC, NC	58.5, 100.3	-0.5, 2.3	53.5, 107.4	-3.2, 1.3	53.5, 107.4	-3.2, 2.3
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	77.53	1.13	90.10	-0.60	82.56	0.44
SD	NC	NC	21.211	1.484	21.496	0.283	19.694	1.422
Median	NC	NC	73.70	1.50	90.10	-0.60	74.90	-0.40
Q1, Q3	NC, NC	NC, NC	58.50, 100.40	-0.50, 2.40	74.90, 105.30	-0.80, -0.40	73.70, 100.40	-0.50, 1.50
Min, Max	NC, NC	NC, NC	58.5, 100.4	-0.5, 2.4	74.9, 105.3	-0.8, -0.4	58.5, 105.3	-0.8, 2.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Weight (kg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	73.30	1.10	90.85	0.15	85.00	0.47
SD	NC	NC	NC	NC	19.870	1.909	17.323	1.457
Median	NC	NC	73.30	1.10	90.85	0.15	76.80	1.10
Q1, Q3	NC, NC	NC, NC	73.30, 73.30	1.10, 1.10	76.80, 104.90	-1.20, 1.50	73.30, 104.90	-1.20, 1.50
Min, Max	NC, NC	NC, NC	73.3, 73.3	1.1, 1.1	76.8, 104.9	-1.2, 1.5	73.3, 104.9	-1.2, 1.5
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	73.80	1.60	108.50	2.40	91.15	2.00
SD	NC	NC	NC	NC	NC	NC	24.537	0.566
Median	NC	NC	73.80	1.60	108.50	2.40	91.15	2.00
Q1, Q3	NC, NC	NC, NC	73.80, 73.80	1.60, 1.60	108.50, 108.50	2.40, 2.40	73.80, 108.50	1.60, 2.40
Min, Max	NC, NC	NC, NC	73.8, 73.8	1.6, 1.6	108.5, 108.5	2.4, 2.4	73.8, 108.5	1.6, 2.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Weight (kg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	73.40	1.20	109.70	3.60	91.55	2.40
SD	NC	NC	NC	NC	NC	NC	25.668	1.697
Median	NC	NC	73.40	1.20	109.70	3.60	91.55	2.40
Q1, Q3	NC, NC	NC, NC	73.40, 73.40	1.20, 1.20	109.70, 109.70	3.60, 3.60	73.40, 109.70	1.20, 3.60
Min, Max	NC, NC	NC, NC	73.4, 73.4	1.2, 1.2	109.7, 109.7	3.6, 3.6	73.4, 109.7	1.2, 3.6
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	73.10	0.90	110.80	4.70	91.95	2.80
SD	NC	NC	NC	NC	NC	NC	26.658	2.687
Median	NC	NC	73.10	0.90	110.80	4.70	91.95	2.80
Q1, Q3	NC, NC	NC, NC	73.10, 73.10	0.90, 0.90	110.80, 110.80	4.70, 4.70	73.10, 110.80	0.90, 4.70
Min, Max	NC, NC	NC, NC	73.1, 73.1	0.9, 0.9	110.8, 110.8	4.7, 4.7	73.1, 110.8	0.9, 4.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Weight (kg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	72.40	0.20	NC	NC	72.40	0.20
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	72.40	0.20	NC	NC	72.40	0.20
Q1, Q3	NC, NC	NC, NC	72.40, 72.40	0.20, 0.20	NC, NC	NC, NC	72.40, 72.40	0.20, 0.20
Min, Max	NC, NC	NC, NC	72.4, 72.4	0.2, 0.2	NC, NC	NC, NC	72.4, 72.4	0.2, 0.2
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	74.20	2.00	NC	NC	74.20	2.00
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	74.20	2.00	NC	NC	74.20	2.00
Q1, Q3	NC, NC	NC, NC	74.20, 74.20	2.00, 2.00	NC, NC	NC, NC	74.20, 74.20	2.00, 2.00
Min, Max	NC, NC	NC, NC	74.2, 74.2	2.0, 2.0	NC, NC	NC, NC	74.2, 74.2	2.0, 2.0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Weight (kg)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	73.40	1.20	NC	NC	73.40	1.20
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	73.40	1.20	NC	NC	73.40	1.20
Q1, Q3	NC, NC	NC, NC	73.40, 73.40	1.20, 1.20	NC, NC	NC, NC	73.40, 73.40	1.20, 1.20
Min, Max	NC, NC	NC, NC	73.4, 73.4	1.2, 1.2	NC, NC	NC, NC	73.4, 73.4	1.2, 1.2
End of Treatment								
Nx	2	2	4	4	8	8	14	14
Mean	65.45	3.60	80.05	-0.33	83.65	-1.04	80.02	-0.17
SD	3.041	7.071	19.859	2.934	20.189	3.521	18.761	3.894
Median	65.45	3.60	82.15	-0.10	84.90	-0.90	75.15	-0.70
Q1, Q3	63.30, 67.60	-1.40, 8.60	64.55, 95.55	-2.75, 2.10	68.00, 99.55	-3.60, 1.20	63.30, 96.60	-3.20, 1.60
Min, Max	63.3, 67.6	-1.4, 8.6	55.3, 100.6	-3.7, 2.6	53.5, 110.8	-6.4, 4.7	53.5, 110.8	-6.4, 8.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Body Mass Index (kg/m2)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	23.15		25.16		26.64		25.48	
SD	2.954		5.857		5.948		5.415	
Median	22.85		25.60		24.80		23.50	
Q1, Q3	21.10, 25.20		19.20, 31.20		21.60, 32.60		20.70, 31.10	
Min, Max	19.9, 27.0		18.1, 32.0		19.6, 35.4		18.1, 35.4	
Cycle 2 Day 1								
Nx	2	2	4	4	8	8	14	14
Mean	21.40	0.30	26.00	-0.05	26.00	-0.18	25.34	-0.07
SD	1.980	0.283	5.694	0.332	5.575	0.661	5.226	0.543
Median	21.40	0.30	27.60	-0.10	24.30	-0.05	24.30	-0.05
Q1, Q3	20.00, 22.80	0.10, 0.50	22.00, 30.00	-0.25, 0.15	21.40, 31.80	-0.50, 0.20	20.50, 30.30	-0.20, 0.40
Min, Max	20.0, 22.8	0.1, 0.5	18.0, 30.8	-0.4, 0.4	19.6, 33.4	-1.4, 0.7	18.0, 33.4	-1.4, 0.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Body Mass Index (kg/m2)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 5 Day 1								
Nx	1	1	4	4	5	5	10	10
Mean	19.40	-0.50	25.58	-0.48	25.66	-0.36	25.00	-0.42
SD	NC	NC	5.132	0.978	5.907	0.336	5.307	0.611
Median	19.40	-0.50	26.60	-0.25	25.60	-0.50	25.65	-0.50
Q1, Q3	19.40, 19.40	-0.50, -0.50	22.10, 29.05	-1.20, 0.25	20.70, 30.40	-0.60, 0.00	19.40, 30.40	-0.60, 0.00
Min, Max	19.4, 19.4	-0.5, -0.5	18.5, 30.6	-1.8, 0.4	19.0, 32.6	-0.7, 0.0	18.5, 32.6	-1.8, 0.4
Cycle 7 Day 1								
Nx	0	0	3	3	5	5	8	8
Mean	NC	NC	24.47	0.13	25.72	-0.30	25.25	-0.14
SD	NC	NC	5.950	0.306	6.150	0.636	5.670	0.555
Median	NC	NC	26.00	0.20	25.50	-0.50	25.75	-0.00
Q1, Q3	NC, NC	NC, NC	17.90, 29.50	-0.20, 0.40	21.00, 30.60	-0.60, 0.30	19.75, 30.05	-0.55, 0.35
Min, Max	NC, NC	NC, NC	17.9, 29.5	-0.2, 0.4	18.5, 33.0	-1.1, 0.4	17.9, 33.0	-1.1, 0.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Body Mass Index (kg/m2)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 9 Day 1								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	24.60	0.27	25.90	-0.20	25.25	0.03
SD	NC	NC	6.089	0.404	7.255	0.794	6.032	0.619
Median	NC	NC	25.80	0.20	26.20	0.10	26.00	0.15
Q1, Q3	NC, NC	NC, NC	18.00, 30.00	-0.10, 0.70	18.50, 33.00	-1.10, 0.40	18.50, 30.00	-0.10, 0.40
Min, Max	NC, NC	NC, NC	18.0, 30.0	-0.1, 0.7	18.5, 33.0	-1.1, 0.4	18.0, 33.0	-1.1, 0.7
Cycle 11 Day 1								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	24.70	0.37	29.15	-0.20	26.48	0.14
SD	NC	NC	6.121	0.416	4.596	0.000	5.473	0.428
Median	NC	NC	26.10	0.50	29.15	-0.20	26.10	-0.10
Q1, Q3	NC, NC	NC, NC	18.00, 30.00	-0.10, 0.70	25.90, 32.40	-0.20, -0.20	25.90, 30.00	-0.20, 0.50
Min, Max	NC, NC	NC, NC	18.0, 30.0	-0.1, 0.7	25.9, 32.4	-0.2, -0.2	18.0, 32.4	-0.2, 0.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Body Mass Index (kg/m2)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 13 Day 1								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	26.00	0.40	29.45	0.10	28.30	0.20
SD	NC	NC	NC	NC	4.031	0.566	3.477	0.436
Median	NC	NC	26.00	0.40	29.45	0.10	26.60	0.40
Q1, Q3	NC, NC	NC, NC	26.00, 26.00	0.40, 0.40	26.60, 32.30	-0.30, 0.50	26.00, 32.30	-0.30, 0.50
Min, Max	NC, NC	NC, NC	26.0, 26.0	0.4, 0.4	26.6, 32.3	-0.3, 0.5	26.0, 32.3	-0.3, 0.5
Cycle 15 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	26.10	0.50	33.40	0.80	29.75	0.65
SD	NC	NC	NC	NC	NC	NC	5.162	0.212
Median	NC	NC	26.10	0.50	33.40	0.80	29.75	0.65
Q1, Q3	NC, NC	NC, NC	26.10, 26.10	0.50, 0.50	33.40, 33.40	0.80, 0.80	26.10, 33.40	0.50, 0.80
Min, Max	NC, NC	NC, NC	26.1, 26.1	0.5, 0.5	33.4, 33.4	0.8, 0.8	26.1, 33.4	0.5, 0.8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Body Mass Index (kg/m2)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 17 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	26.00	0.40	33.70	1.10	29.85	0.75
SD	NC	NC	NC	NC	NC	NC	5.445	0.495
Median	NC	NC	26.00	0.40	33.70	1.10	29.85	0.75
Q1, Q3	NC, NC	NC, NC	26.00, 26.00	0.40, 0.40	33.70, 33.70	1.10, 1.10	26.00, 33.70	0.40, 1.10
Min, Max	NC, NC	NC, NC	26.0, 26.0	0.4, 0.4	33.7, 33.7	1.1, 1.1	26.0, 33.7	0.4, 1.1
Cycle 19 Day 1								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	25.90	0.30	34.10	1.50	30.00	0.90
SD	NC	NC	NC	NC	NC	NC	5.798	0.849
Median	NC	NC	25.90	0.30	34.10	1.50	30.00	0.90
Q1, Q3	NC, NC	NC, NC	25.90, 25.90	0.30, 0.30	34.10, 34.10	1.50, 1.50	25.90, 34.10	0.30, 1.50
Min, Max	NC, NC	NC, NC	25.9, 25.9	0.3, 0.3	34.1, 34.1	1.5, 1.5	25.9, 34.1	0.3, 1.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Body Mass Index (kg/m2)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 21 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	25.70	0.10	NC	NC	25.70	0.10
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	25.70	0.10	NC	NC	25.70	0.10
Q1, Q3	NC, NC	NC, NC	25.70, 25.70	0.10, 0.10	NC, NC	NC, NC	25.70, 25.70	0.10, 0.10
Min, Max	NC, NC	NC, NC	25.7, 25.7	0.1, 0.1	NC, NC	NC, NC	25.7, 25.7	0.1, 0.1
Cycle 23 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	26.30	0.70	NC	NC	26.30	0.70
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	26.30	0.70	NC	NC	26.30	0.70
Q1, Q3	NC, NC	NC, NC	26.30, 26.30	0.70, 0.70	NC, NC	NC, NC	26.30, 26.30	0.70, 0.70
Min, Max	NC, NC	NC, NC	26.3, 26.3	0.7, 0.7	NC, NC	NC, NC	26.3, 26.3	0.7, 0.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.1
Summary of Vital Signs by Treatment Group and Timepoint
(Safety Set)

Parameter: Body Mass Index (kg/m2)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 25 Day 1								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	26.00	0.40	NC	NC	26.00	0.40
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	26.00	0.40	NC	NC	26.00	0.40
Q1, Q3	NC, NC	NC, NC	26.00, 26.00	0.40, 0.40	NC, NC	NC, NC	26.00, 26.00	0.40, 0.40
Min, Max	NC, NC	NC, NC	26.0, 26.0	0.4, 0.4	NC, NC	NC, NC	26.0, 26.0	0.4, 0.4
End of Treatment								
Nx	2	2	4	4	8	8	14	14
Mean	22.50	1.40	25.93	-0.13	26.08	-0.34	25.52	-0.03
SD	4.384	2.687	6.276	0.866	6.095	1.117	5.676	1.333
Median	22.50	1.40	28.05	-0.05	25.15	-0.25	25.85	-0.25
Q1, Q3	19.40, 25.60	-0.50, 3.30	21.55, 30.30	-0.85, 0.60	20.85, 32.00	-1.20, 0.35	19.40, 30.60	-1.10, 0.50
Min, Max	19.4, 25.6	-0.5, 3.3	17.0, 30.6	-1.1, 0.7	18.5, 34.1	-2.0, 1.5	17.0, 34.1	-2.0, 3.3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	74.9		77.3		82.0		79.1	
SD	21.91		17.87		12.76		15.81	
Median	67.5		74.3		85.3		78.7	
Q1, Q3	62.0, 87.8		60.7, 92.0		77.0, 91.7		61.7, 91.7	
Min, Max	58, 107		60, 104		61, 100		58, 107	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	75.6	0.7	73.6	-3.7	80.2	-1.9	77.1	-2.0
SD	18.10	6.00	17.91	3.72	12.38	6.46	14.96	5.54
Median	71.8	0.3	72.7	-4.7	81.0	-1.8	74.7	-2.3
Q1, Q3	63.5, 87.7	-3.0, 4.3	56.3, 92.0	-6.3, -1.7	71.7, 91.3	-5.3, -0.3	69.0, 91.3	-5.3, 0.3
Min, Max	58, 101	-6, 8	54, 96	-8, 3	58, 99	-15, 8	54, 101	-15, 8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 2 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	75.4	0.5	76.6	-0.7	79.3	-2.7	77.7	-1.4
SD	19.31	2.81	15.41	5.56	16.67	6.88	15.97	5.79
Median	69.7	1.7	70.7	0.0	80.7	-1.5	72.3	0.0
Q1, Q3	63.7, 87.2	-1.2, 2.2	64.7, 92.0	-4.0, 4.7	68.7, 91.3	-5.0, 1.3	66.3, 91.3	-4.0, 2.3
Min, Max	59, 103	-4, 2	57, 94	-10, 6	55, 105	-19, 5	55, 105	-19, 6
Cycle 1 Day 1, 3 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	74.2	-0.8	74.6	-2.7	82.7	0.7	78.4	-0.7
SD	20.36	2.95	17.06	3.66	14.69	5.40	16.26	4.56
Median	68.7	-1.3	71.0	-3.3	84.8	0.5	75.3	-1.7
Q1, Q3	61.8, 86.5	-2.7, 1.2	57.0, 90.7	-5.7, 1.7	71.0, 92.7	-3.3, 2.0	67.7, 90.7	-3.7, 1.7
Min, Max	56, 103	-4, 3	55, 97	-7, 3	57, 109	-6, 10	55, 109	-7, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	77.3	2.3	76.1	-1.2	80.5	-1.5	78.4	-0.7
SD	21.85	5.41	16.88	3.73	15.03	4.52	16.22	4.47
Median	73.7	1.3	72.0	-2.0	81.8	-0.2	78.0	0.0
Q1, Q3	63.0, 91.5	-1.5, 6.2	58.0, 93.3	-3.3, 1.3	74.3, 91.3	-2.7, 2.0	65.3, 91.3	-2.7, 2.0
Min, Max	55, 107	-3, 10	58, 97	-7, 5	52, 103	-10, 3	52, 107	-10, 10
Cycle 1 Day 1, 6 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	80.6	5.7	75.0	-2.3	80.8	-1.3	78.8	-0.3
SD	24.66	4.86	13.00	7.79	13.98	6.38	15.41	7.00
Median	75.5	7.2	70.0	1.0	80.0	0.0	76.0	1.0
Q1, Q3	65.7, 95.5	2.5, 8.8	63.3, 86.0	-4.3, 2.3	69.7, 93.3	-2.3, 4.3	66.0, 86.0	-2.3, 4.3
Min, Max	56, 115	-1, 10	61, 94	-18, 5	62, 104	-16, 5	56, 115	-18, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 8 Hours Post-Dose								
Nx	4	4	6	6	10	10	20	20
Mean	82.1	7.2	73.3	-2.1	81.1	-0.9	79.0	0.4
SD	25.13	4.72	14.36	4.87	13.54	4.38	15.98	5.60
Median	75.3	7.7	68.0	-1.7	81.2	0.7	76.7	0.8
Q1, Q3	66.3, 97.8	3.2, 11.2	61.3, 86.0	-6.0, 0.7	73.3, 93.7	-2.3, 2.3	64.7, 90.7	-3.0, 2.7
Min, Max	60, 118	2, 11	61, 96	-8, 5	59, 101	-12, 3	59, 118	-12, 11
Cycle 1 Day 1, 12 Hours Post-Dose								
Nx	4	4	5	5	10	10	19	19
Mean	82.2	7.3	77.3	-0.9	81.6	-0.4	80.6	1.1
SD	23.15	6.88	14.76	6.34	16.74	8.68	16.80	8.08
Median	80.2	8.8	71.3	-2.3	81.5	-0.2	78.7	0.0
Q1, Q3	67.3, 97.0	1.8, 12.7	69.0, 89.7	-3.0, 0.0	67.7, 91.3	-2.7, 3.7	67.7, 91.3	-2.7, 6.0
Min, Max	56, 112	-2, 13	61, 96	-8, 9	61, 114	-20, 14	56, 114	-20, 14

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 2, Pre-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	77.8	2.9	75.7	-1.6	81.2	-0.9	78.7	-0.4
SD	20.87	5.42	13.50	8.21	11.59	4.57	13.67	6.07
Median	72.0	1.3	79.7	0.7	81.3	-0.2	77.7	0.3
Q1, Q3	63.5, 92.2	-0.7, 6.5	62.7, 87.0	-2.0, 2.7	71.3, 89.3	-2.3, 1.7	67.0, 87.0	-1.7, 2.7
Min, Max	60, 107	-2, 11	59, 93	-19, 5	64, 100	-10, 6	59, 107	-19, 11
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	8	8	17	17
Mean	79.8	-0.9	74.7	-0.2	80.4	-2.7	78.3	-1.5
SD	20.68	4.55	21.94	5.85	16.95	4.33	18.36	4.79
Median	73.0	-3.0	65.2	1.0	82.2	-2.7	78.3	-2.7
Q1, Q3	63.3, 103.0	-4.0, 4.3	60.0, 96.0	-6.3, 4.0	68.7, 93.7	-5.8, 0.2	63.3, 96.0	-4.0, 2.7
Min, Max	63, 103	-4, 4	54, 108	-8, 7	53, 101	-9, 4	53, 108	-9, 7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 6, 1 Hour Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	74.6	-6.1	74.3	-0.6	79.0	-3.4	76.7	-2.9
SD	22.91	1.84	20.20	4.94	15.41	5.25	17.30	4.95
Median	62.0	-6.0	67.0	-2.2	80.7	-4.3	72.8	-4.0
Q1, Q3	60.7, 101.0	-8.0, -4.3	57.0, 98.0	-3.7, 0.0	71.7, 87.3	-4.7, 0.3	60.7, 95.7	-4.7, 0.0
Min, Max	61, 101	-8, -4	56, 100	-4, 9	57, 102	-15, 3	56, 102	-15, 9
Cycle 1 Day 6, 2 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	79.6	-1.1	74.8	-0.1	80.4	-2.0	78.4	-1.2
SD	21.91	1.84	16.03	8.74	17.08	6.61	16.62	6.65
Median	69.7	-2.0	71.8	0.0	83.3	-2.0	72.7	-1.7
Q1, Q3	64.3, 104.7	-2.3, 1.0	62.3, 90.7	-5.3, 7.7	71.0, 95.3	-4.7, 3.7	64.3, 95.3	-4.7, 3.7
Min, Max	64, 105	-2, 1	55, 97	-13, 11	57, 106	-16, 6	55, 106	-16, 11

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 6, 3 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	82.7	2.0	75.0	0.2	81.1	-1.3	79.4	-0.2
SD	21.93	2.60	17.41	7.61	17.18	6.07	17.17	6.06
Median	73.7	0.7	66.5	0.7	80.3	-0.7	75.5	0.5
Q1, Q3	66.7, 107.7	0.3, 5.0	65.3, 95.0	-7.0, 5.7	69.0, 94.0	-5.0, 2.3	65.7, 95.0	-5.0, 5.0
Min, Max	67, 108	0, 5	58, 99	-9, 10	57, 108	-10, 8	57, 108	-10, 10
Cycle 1 Day 6, 4 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	84.0	3.3	77.5	2.7	81.6	-0.8	80.6	1.0
SD	22.26	2.40	16.45	6.53	15.77	7.67	16.15	6.68
Median	72.3	2.7	70.3	3.7	81.7	-3.0	74.8	0.7
Q1, Q3	70.0, 109.7	1.3, 6.0	67.3, 97.3	-2.0, 7.3	71.7, 89.3	-3.7, 7.0	68.3, 97.3	-3.3, 7.3
Min, Max	70, 110	1, 6	61, 99	-7, 10	58, 107	-11, 10	58, 110	-11, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 6, 6 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	85.3	4.7	79.3	4.4	81.7	-0.7	81.5	1.9
SD	23.13	0.33	17.81	7.78	16.39	5.73	16.94	6.37
Median	73.3	4.7	71.8	3.8	81.0	-0.3	76.2	2.3
Q1, Q3	70.7, 112.0	4.3, 5.0	70.7, 100.3	-2.0, 11.3	75.7, 95.3	-4.3, 3.7	70.7, 97.0	-2.0, 5.0
Min, Max	71, 112	4, 5	59, 102	-4, 13	56, 107	-12, 7	56, 112	-12, 13
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	81.8	1.1	62.0	-2.0	83.7	-1.7	76.6	-1.1
SD	28.68	7.24	1.76	5.99	9.12	7.00	16.60	6.31
Median	68.7	2.3	62.3	0.2	85.3	-2.2	71.0	-0.7
Q1, Q3	62.0, 114.7	-6.7, 7.7	60.7, 63.3	-6.0, 2.0	75.7, 88.7	-6.0, 4.7	63.0, 86.0	-6.0, 2.3
Min, Max	62, 115	-7, 8	60, 64	-11, 2	71, 96	-12, 7	60, 115	-12, 8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	81.2	0.6	61.9	-2.1	78.4	-7.0	74.0	-3.7
SD	22.63	0.38	3.48	5.02	9.57	8.23	14.07	6.74
Median	69.0	0.3	62.3	-0.8	81.7	-7.3	69.0	-2.3
Q1, Q3	67.3, 107.3	0.3, 1.0	59.5, 64.3	-6.0, 1.8	71.7, 83.7	-14.3, -2.3	63.0, 83.0	-8.7, 1.0
Min, Max	67, 107	0, 1	57, 66	-9, 2	63, 89	-16, 5	57, 107	-16, 5
Cycle 1 Day 14, 2 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	82.6	1.9	63.5	-0.5	81.3	-4.1	76.1	-1.6
SD	20.11	2.91	4.61	8.85	11.99	9.68	14.47	8.16
Median	73.0	2.7	63.8	0.5	84.2	-0.3	69.0	0.7
Q1, Q3	69.0, 105.7	-1.3, 4.3	60.2, 66.8	-7.3, 6.3	66.7, 93.0	-10.3, 1.3	66.7, 84.3	-3.0, 4.0
Min, Max	69, 106	-1, 4	58, 69	-12, 9	67, 93	-21, 6	58, 106	-21, 9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 14, 3 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	84.6	3.9	62.5	-1.5	80.1	-5.3	75.7	-2.0
SD	23.50	0.69	4.47	6.13	9.18	8.23	14.82	7.20
Median	72.0	3.7	63.7	-1.8	84.0	-4.2	70.0	-2.0
Q1, Q3	70.0, 111.7	3.3, 4.7	59.0, 66.0	-6.2, 3.2	68.7, 87.0	-8.3, -2.0	66.0, 84.7	-4.7, 3.7
Min, Max	70, 112	3, 5	57, 66	-8, 6	68, 89	-19, 6	57, 112	-19, 6
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	84.1	3.4	61.7	-2.3	80.8	-4.6	75.7	-2.1
SD	23.44	1.58	2.92	8.21	8.70	7.06	14.88	6.99
Median	73.3	4.0	60.5	-0.8	80.5	-2.7	73.3	-1.0
Q1, Q3	68.0, 111.0	1.7, 4.7	60.0, 63.3	-7.3, 2.7	73.7, 90.3	-4.7, -1.0	66.0, 80.7	-3.3, 1.7
Min, Max	68, 111	2, 5	60, 66	-14, 6	69, 91	-18, 2	60, 111	-18, 6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 14, 6 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	84.1	3.4	63.6	-0.4	80.3	-5.1	76.1	-1.7
SD	18.69	4.14	4.84	8.57	10.57	9.15	13.71	8.30
Median	74.3	5.7	63.0	-0.5	79.5	-1.0	74.3	-0.3
Q1, Q3	72.3, 105.7	-1.3, 6.0	60.3, 66.8	-6.5, 5.7	75.3, 91.7	-5.0, 0.0	64.0, 80.3	-2.3, 1.3
Min, Max	72, 106	-1, 6	58, 70	-11, 10	64, 92	-23, 0	58, 106	-23, 10
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	6	6	12	12
Mean	73.2	5.7	64.3	0.3	72.6	-5.1	69.9	-1.5
SD	3.06	4.71	9.77	14.10	12.37	8.49	10.65	10.32
Median	73.2	5.7	63.2	1.3	71.5	-3.7	69.8	-1.2
Q1, Q3	71.0, 75.3	2.3, 9.0	56.3, 72.3	-10.8, 11.5	65.0, 85.3	-6.3, 0.0	61.3, 76.2	-5.7, 5.8
Min, Max	71, 75	2, 9	55, 76	-17, 15	55, 87	-21, 4	55, 87	-21, 15

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 2 Day 1, 1 Hour Post-Dose								
Nx	2	2	4	4	6	6	12	12
Mean	77.0	9.5	64.8	0.8	75.6	-2.1	72.2	0.8
SD	1.41	3.06	4.17	9.62	11.35	11.68	9.67	10.31
Median	77.0	9.5	63.5	3.0	76.0	2.3	69.3	3.7
Q1, Q3	76.0, 78.0	7.3, 11.7	61.8, 67.8	-5.3, 7.0	65.0, 86.7	-5.0, 5.3	64.0, 81.0	-1.8, 7.2
Min, Max	76, 78	7, 12	62, 71	-13, 10	63, 87	-24, 7	62, 87	-24, 12
Cycle 3 Day 1, Pre-Dose								
Nx	0	0	4	4	4	4	8	8
Mean	NC	NC	61.7	-2.3	76.4	-3.3	69.0	-2.8
SD	NC	NC	7.55	3.63	6.79	13.84	10.31	9.38
Median	NC	NC	60.8	-1.3	77.0	-3.5	69.8	-1.3
Q1, Q3	NC, NC	NC, NC	57.0, 66.3	-5.0, 0.3	71.2, 81.7	-13.7, 7.2	60.8, 77.0	-7.7, 0.8
Min, Max	NC, NC	NC, NC	53, 72	-7, 1	68, 84	-19, 13	53, 84	-19, 13

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 3 Day 1, 1 Hour Post-Dose								
Nx	1	1	4	4	4	4	9	9
Mean	73.3	7.0	60.2	-3.8	77.0	-2.7	69.1	-2.1
SD	NC	NC	6.30	4.57	12.83	17.81	12.25	11.78
Median	73.3	7.0	59.8	-5.3	79.8	1.7	67.7	-3.3
Q1, Q3	73.3, 73.3	7.0, 7.0	55.2, 65.2	-7.0, -0.7	67.2, 86.8	-15.3, 10.0	60.0, 74.3	-6.7, 6.7
Min, Max	73, 73	7, 7	53, 68	-7, 3	60, 88	-27, 13	53, 88	-27, 13
Cycle 5 Day 1, Pre-Dose								
Nx	0	0	3	3	4	4	7	7
Mean	NC	NC	60.7	-4.3	76.3	0.8	69.6	-1.4
SD	NC	NC	2.89	9.94	16.46	12.59	14.41	10.94
Median	NC	NC	59.0	-1.7	83.0	-3.0	64.0	-1.7
Q1, Q3	NC, NC	NC, NC	59.0, 64.0	-15.3, 4.0	66.0, 86.5	-7.2, 8.8	59.0, 86.0	-9.7, 4.0
Min, Max	NC, NC	NC, NC	59, 64	-15, 4	52, 87	-10, 19	52, 87	-15, 19

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	2	2	4	4	6	6
Mean	NC	NC	66.5	-1.0	74.3	-1.2	71.7	-1.1
SD	NC	NC	3.54	6.13	19.60	12.04	15.78	9.72
Median	NC	NC	66.5	-1.0	67.0	0.7	66.5	0.7
Q1, Q3	NC, NC	NC, NC	64.0, 69.0	-5.3, 3.3	62.0, 86.5	-9.5, 7.2	64.0, 70.0	-5.3, 3.3
Min, Max	NC, NC	NC, NC	64, 69	-5, 3	60, 103	-17, 11	60, 103	-17, 11
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	64.7	-0.7	71.0	-9.0	67.8	-4.8
SD	NC	NC	3.79	9.82	19.31	10.48	12.92	10.16
Median	NC	NC	63.0	1.3	67.0	-7.0	65.0	-3.3
Q1, Q3	NC, NC	NC, NC	62.0, 69.0	-11.3, 8.0	54.0, 92.0	-20.3, 0.3	62.0, 69.0	-11.3, 1.3
Min, Max	NC, NC	NC, NC	62, 69	-11, 8	54, 92	-20, 0	54, 92	-20, 8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	67.0	1.7	61.0	-13.2	64.6	-4.3
SD	NC	NC	4.36	6.36	0.00	18.62	4.51	13.15
Median	NC	NC	69.0	1.0	61.0	-13.2	62.0	0.0
Q1, Q3	NC, NC	NC, NC	62.0, 70.0	-4.3, 8.3	61.0, 61.0	-26.3, 0.0	61.0, 69.0	-4.3, 1.0
Min, Max	NC, NC	NC, NC	62, 70	-4, 8	61, 61	-26, 0	61, 70	-26, 8
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	61.0	0.0	59.5	-14.7	60.0	-9.8
SD	NC	NC	NC	NC	4.95	13.67	3.61	12.85
Median	NC	NC	61.0	0.0	59.5	-14.7	61.0	-5.0
Q1, Q3	NC, NC	NC, NC	61.0, 61.0	0.0, 0.0	56.0, 63.0	-24.3, -5.0	56.0, 63.0	-24.3, 0.0
Min, Max	NC, NC	NC, NC	61, 61	0, 0	56, 63	-24, -5	56, 63	-24, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	69.0	8.0	68.0	-19.3	68.5	-5.7
SD	NC	NC	NC	NC	NC	NC	0.71	19.33
Median	NC	NC	69.0	8.0	68.0	-19.3	68.5	-5.7
Q1, Q3	NC, NC	NC, NC	69.0, 69.0	8.0, 8.0	68.0, 68.0	-19.3, -19.3	68.0, 69.0	-19.3, 8.0
Min, Max	NC, NC	NC, NC	69, 69	8, 8	68, 68	-19, -19	68, 69	-19, 8
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	61.0	0.0	69.0	-18.3	65.0	-9.2
SD	NC	NC	NC	NC	NC	NC	5.66	12.96
Median	NC	NC	61.0	0.0	69.0	-18.3	65.0	-9.2
Q1, Q3	NC, NC	NC, NC	61.0, 61.0	0.0, 0.0	69.0, 69.0	-18.3, -18.3	61.0, 69.0	-18.3, 0.0
Min, Max	NC, NC	NC, NC	61, 61	0, 0	69, 69	-18, -18	61, 69	-18, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Value	Value		Value		Value		Value	
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	69.0	8.0	83.0	-4.3	76.0	1.8
SD	NC	NC	NC	NC	NC	NC	9.90	8.72
Median	NC	NC	69.0	8.0	83.0	-4.3	76.0	1.8
Q1, Q3	NC, NC	NC, NC	69.0, 69.0	8.0, 8.0	83.0, 83.0	-4.3, -4.3	69.0, 83.0	-4.3, 8.0
Min, Max	NC, NC	NC, NC	69, 69	8, 8	83, 83	-4, -4	69, 83	-4, 8
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	67.0	6.0	NC	NC	67.0	6.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	67.0	6.0	NC	NC	67.0	6.0
Q1, Q3	NC, NC	NC, NC	67.0, 67.0	6.0, 6.0	NC, NC	NC, NC	67.0, 67.0	6.0, 6.0
Min, Max	NC, NC	NC, NC	67, 67	6, 6	NC, NC	NC, NC	67, 67	6, 6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: ECG Mean Heart Rate (beats/min)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	63.0	2.0	NC	NC	63.0	2.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	63.0	2.0	NC	NC	63.0	2.0
Q1, Q3	NC, NC	NC, NC	63.0, 63.0	2.0, 2.0	NC, NC	NC, NC	63.0, 63.0	2.0, 2.0
Min, Max	NC, NC	NC, NC	63, 63	2, 2	NC, NC	NC, NC	63, 63	2, 2
End of Treatment, Pre-Dose								
Nx	2	2	3	3	8	8	13	13
Mean	83.5	-4.3	58.3	-6.8	78.6	0.1	74.7	-2.2
SD	43.13	16.03	4.04	5.67	17.83	9.43	20.82	9.40
Median	83.5	-4.3	59.0	-7.0	81.5	-4.5	67.0	-4.7
Q1, Q3	53.0, 114.0	-15.7, 7.0	54.0, 62.0	-12.3, -1.0	62.0, 90.5	-5.7, 8.5	57.0, 88.0	-7.0, 2.7
Min, Max	53, 114	-16, 7	54, 62	-12, -1	55, 106	-10, 14	53, 114	-16, 14

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		9		20	
Mean	151.4		162.1		163.4		160.6	
SD	10.72		22.37		24.58		21.28	
Median	153.3		159.7		161.3		160.0	
Q1, Q3	144.7, 158.2		152.7, 161.0		160.0, 182.0		152.7, 161.8	
Min, Max	137, 162		135, 208		126, 204		126, 208	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	9	9	20	20
Mean	149.3	-2.2	165.4	3.3	169.4	6.0	164.0	3.4
SD	10.72	5.00	28.60	10.98	35.50	15.09	29.45	12.15
Median	153.5	-1.3	156.7	-2.7	172.0	1.3	156.7	0.3
Q1, Q3	143.3, 155.2	-6.0, 1.7	150.7, 183.0	-3.3, 12.3	144.0, 184.0	-0.7, 10.7	147.3, 178.8	-3.2, 10.7
Min, Max	133, 157	-9, 3	132, 221	-9, 22	127, 241	-17, 37	127, 241	-17, 37

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 2 Hours Post-Dose								
Nx	4	4	7	7	9	9	20	20
Mean	149.9	-1.5	163.7	1.5	169.1	5.7	163.4	2.8
SD	10.34	2.52	26.84	7.93	32.03	9.16	27.01	8.04
Median	153.7	-1.3	158.7	0.0	163.3	2.7	158.2	1.7
Q1, Q3	144.0, 155.8	-3.3, 0.3	147.3, 172.0	-0.3, 10.3	156.3, 191.0	2.0, 8.7	150.3, 170.3	-1.3, 7.8
Min, Max	135, 158	-5, 1	135, 219	-13, 11	128, 231	-5, 27	128, 231	-13, 27
Cycle 1 Day 1, 3 Hours Post-Dose								
Nx	4	4	7	7	10	9	21	20
Mean	148.5	-2.9	167.3	5.2	154.3	1.1	157.5	1.7
SD	14.16	6.03	31.14	12.12	45.79	15.06	36.33	12.52
Median	155.0	-3.2	156.0	-0.7	154.0	4.0	156.0	-0.3
Q1, Q3	140.7, 156.3	-7.8, 2.0	154.7, 184.3	-4.0, 21.3	130.0, 190.0	-3.3, 7.3	134.0, 168.7	-4.7, 6.7
Min, Max	127, 157	-9, 4	134, 230	-5, 23	62, 226	-29, 22	62, 230	-29, 23

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	9	9	20	20
Mean	150.8	-0.7	165.8	3.6	170.6	7.2	165.0	4.4
SD	13.95	6.91	30.44	11.26	34.42	14.74	29.66	12.19
Median	148.7	0.3	155.0	-1.0	162.7	1.3	157.7	-0.3
Q1, Q3	140.3, 161.2	-5.0, 3.7	151.7, 182.0	-4.7, 18.7	158.7, 185.3	-1.7, 13.7	147.8, 178.8	-2.0, 10.2
Min, Max	137, 169	-10, 7	134, 227	-6, 21	128, 240	-8, 36	128, 240	-10, 36
Cycle 1 Day 1, 6 Hours Post-Dose								
Nx	4	4	7	7	9	9	20	20
Mean	152.5	1.1	164.3	2.1	169.5	6.1	164.3	3.7
SD	9.29	3.21	22.76	7.35	34.03	12.31	26.59	9.36
Median	156.3	2.3	158.0	3.0	163.7	2.3	158.7	2.5
Q1, Q3	147.3, 157.7	-0.8, 3.0	151.3, 173.0	-5.0, 7.3	158.7, 181.3	-1.3, 3.3	153.0, 168.5	-2.0, 5.2
Min, Max	139, 159	-4, 3	142, 211	-9, 12	129, 236	-3, 32	129, 236	-9, 32

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 1, 8 Hours Post-Dose								
Nx	4	4	6	6	9	9	19	19
Mean	145.1	-6.3	169.9	7.3	162.6	-0.8	161.2	0.6
SD	14.07	6.22	30.95	11.31	21.79	8.22	24.37	9.94
Median	149.8	-8.3	159.0	2.3	160.0	-1.3	158.7	-0.7
Q1, Q3	135.0, 155.2	-10.3, -2.3	156.7, 188.3	-0.7, 14.0	156.0, 180.3	-4.0, 6.0	144.7, 180.3	-5.3, 6.0
Min, Max	125, 155	-11, 3	134, 222	-1, 27	128, 188	-17, 11	125, 222	-17, 27
Cycle 1 Day 1, 12 Hours Post-Dose								
Nx	4	4	5	5	8	8	17	17
Mean	150.0	-1.4	170.1	5.6	156.5	-1.8	159.0	0.5
SD	8.99	3.29	37.34	13.89	24.90	12.62	26.40	11.47
Median	153.7	0.0	154.7	-2.0	155.0	-2.3	154.7	-2.0
Q1, Q3	144.7, 155.3	-3.2, 0.3	152.7, 181.3	-4.0, 20.3	134.3, 174.0	-6.7, 6.7	136.7, 166.0	-4.7, 6.0
Min, Max	137, 156	-6, 1	133, 229	-7, 21	127, 198	-26, 16	127, 229	-26, 21

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 2, Pre-Dose								
Nx	4	4	7	7	10	9	21	20
Mean	150.4	-1.0	163.7	1.5	171.8	4.1	165.0	2.2
SD	9.80	1.15	27.52	13.71	31.15	8.31	27.29	9.63
Median	151.7	-1.3	154.7	6.7	167.7	3.3	161.0	1.3
Q1, Q3	144.0, 156.8	-1.7, -0.3	142.0, 183.5	-11.7, 8.0	156.0, 187.3	-2.0, 5.3	142.7, 179.7	-3.0, 7.0
Min, Max	137, 161	-2, 1	141, 215	-18, 23	129, 227	-4, 23	129, 227	-18, 23
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	7	7	16	16
Mean	156.1	5.6	169.2	6.7	167.2	-1.2	165.9	3.0
SD	16.21	4.54	29.05	7.35	24.69	9.31	24.17	8.39
Median	154.7	4.0	162.2	6.0	166.0	4.0	162.2	4.3
Q1, Q3	140.7, 173.0	2.0, 10.7	160.0, 179.0	1.3, 11.3	152.7, 186.0	-8.7, 6.0	153.7, 176.0	-0.7, 7.7
Min, Max	141, 173	2, 11	132, 220	-3, 18	134, 210	-17, 8	132, 220	-17, 18

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 1 Hour Post-Dose								
Nx	3	3	6	6	8	8	17	17
Mean	157.1	6.6	171.7	9.2	163.8	-3.6	165.4	2.7
SD	17.79	6.24	33.65	13.83	25.35	11.92	26.52	12.85
Median	154.7	4.0	169.2	8.5	157.2	-3.5	158.7	2.0
Q1, Q3	140.7, 176.0	2.0, 13.7	149.3, 187.7	-3.3, 18.7	147.7, 177.8	-13.0, 7.3	149.3, 179.7	-5.3, 11.0
Min, Max	141, 176	2, 14	129, 225	-5, 28	135, 210	-21, 11	129, 225	-21, 28
Cycle 1 Day 6, 2 Hours Post-Dose								
Nx	3	3	6	6	8	8	17	17
Mean	154.6	4.0	168.9	6.4	165.5	-1.8	164.8	2.1
SD	22.63	9.68	33.06	12.85	26.53	12.70	27.20	12.21
Median	157.3	4.7	163.2	3.3	164.3	4.3	164.0	4.7
Q1, Q3	130.7, 175.7	-6.0, 13.3	149.0, 187.0	-3.7, 15.0	146.0, 180.8	-14.7, 6.0	147.3, 175.7	-6.0, 6.7
Min, Max	131, 176	-6, 13	128, 223	-7, 27	131, 211	-20, 14	128, 223	-20, 27

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 3 Hours Post-Dose								
Nx	3	3	6	6	8	8	17	17
Mean	153.7	3.1	166.9	4.4	167.3	-0.0	164.7	2.1
SD	22.84	10.12	32.07	7.75	20.72	10.55	24.54	9.20
Median	154.0	1.3	161.3	1.7	168.7	2.0	162.0	2.0
Q1, Q3	130.7, 176.3	-6.0, 14.0	154.0, 165.0	1.0, 5.3	157.7, 182.3	-10.3, 8.5	154.0, 174.7	-2.7, 6.0
Min, Max	131, 176	-6, 14	132, 228	-3, 19	128, 193	-14, 13	128, 228	-14, 19
Cycle 1 Day 6, 4 Hours Post-Dose								
Nx	3	3	6	6	8	8	17	17
Mean	153.0	2.4	176.9	14.4	161.7	-5.6	165.5	2.9
SD	17.19	4.44	38.28	19.38	19.44	9.52	27.30	15.66
Median	154.0	1.3	163.5	6.5	161.0	-5.7	158.0	1.3
Q1, Q3	135.3, 169.7	-1.3, 7.3	157.7, 206.0	-0.7, 29.7	149.0, 176.2	-14.3, 3.7	152.0, 169.7	-3.3, 6.0
Min, Max	135, 170	-1, 7	133, 238	-2, 46	132, 189	-18, 6	132, 238	-18, 46

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 6 Hours Post-Dose								
Nx	3	3	6	6	8	8	17	17
Mean	154.4	3.9	168.2	5.7	163.2	-4.1	163.4	0.8
SD	14.37	3.17	32.50	10.38	20.56	11.42	23.76	10.72
Median	153.3	4.0	163.3	6.5	161.3	-0.7	161.3	1.3
Q1, Q3	140.7, 169.3	0.7, 7.0	150.0, 174.3	-3.3, 14.7	152.0, 176.5	-13.7, 4.3	150.0, 169.3	-3.3, 7.3
Min, Max	141, 169	1, 7	131, 227	-9, 19	133, 193	-23, 10	131, 227	-23, 19
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	160.8	10.2	175.6	5.4	159.1	-4.2	164.5	2.1
SD	18.08	6.94	29.87	10.23	20.94	6.09	22.79	9.46
Median	157.3	8.0	166.8	5.3	160.5	-6.0	157.3	2.7
Q1, Q3	144.7, 180.3	4.7, 18.0	153.5, 197.7	-2.2, 13.0	151.3, 173.3	-8.7, 2.7	152.0, 178.7	-6.7, 8.0
Min, Max	145, 180	5, 18	152, 217	-7, 18	124, 185	-11, 4	124, 217	-11, 18

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	154.0	3.4	172.8	2.7	160.5	-2.7	162.8	0.4
SD	25.67	12.89	33.50	9.30	22.12	6.28	25.49	8.64
Median	154.7	2.0	157.5	0.7	162.7	-3.7	157.0	-3.3
Q1, Q3	128.0, 179.3	-8.7, 17.0	155.2, 190.5	-4.7, 10.0	151.3, 180.7	-8.7, 0.3	153.3, 179.3	-5.3, 5.3
Min, Max	128, 179	-9, 17	153, 223	-5, 15	123, 182	-9, 8	123, 223	-9, 17
Cycle 1 Day 14, 2 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	154.7	4.1	180.0	9.8	158.6	-4.7	164.3	1.8
SD	26.03	13.18	33.96	8.89	22.46	6.29	27.08	10.44
Median	156.0	3.3	167.7	7.8	155.2	-5.2	160.3	2.3
Q1, Q3	128.0, 180.0	-8.7, 17.7	158.5, 201.5	2.8, 16.8	148.0, 179.7	-10.0, -1.0	150.0, 179.7	-6.0, 5.3
Min, Max	128, 180	-9, 18	155, 230	2, 21	126, 187	-12, 5	126, 230	-12, 21

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 3 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	150.4	-0.1	179.9	9.8	161.9	-1.3	164.8	2.4
SD	26.18	13.23	32.43	8.00	27.42	11.04	28.67	11.06
Median	154.0	1.3	168.3	8.8	160.3	-2.5	161.3	2.7
Q1, Q3	122.7, 174.7	-14.0, 12.3	158.7, 201.2	3.0, 16.5	147.3, 182.3	-10.7, 2.7	154.0, 175.3	-3.3, 12.3
Min, Max	123, 175	-14, 12	156, 227	3, 19	121, 200	-13, 18	121, 227	-14, 19
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	153.0	2.4	179.8	9.6	161.4	-1.8	165.1	2.7
SD	22.84	10.12	35.20	10.12	24.33	9.03	27.54	10.13
Median	153.3	0.7	165.3	6.8	158.2	-4.0	162.0	1.0
Q1, Q3	130.0, 175.7	-6.7, 13.3	159.2, 200.3	2.3, 16.8	148.7, 180.7	-8.7, 3.7	151.3, 175.7	-4.7, 10.0
Min, Max	130, 176	-7, 13	156, 232	1, 24	127, 195	-11, 13	127, 232	-11, 24

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 6 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	153.3	2.8	162.9	-7.3	162.2	-1.1	160.4	-2.1
SD	25.06	12.17	10.03	28.35	24.77	9.64	20.04	16.72
Median	155.3	2.7	159.3	1.3	162.2	-4.0	158.7	0.0
Q1, Q3	127.3, 177.3	-9.3, 15.0	157.0, 168.8	-24.2, 9.7	148.0, 178.7	-6.7, 5.7	155.3, 177.3	-6.7, 5.7
Min, Max	127, 177	-9, 15	155, 178	-48, 17	125, 197	-12, 15	125, 197	-48, 17
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	5	5	11	11
Mean	157.0	-0.5	174.3	4.2	152.3	-0.0	161.2	1.4
SD	10.84	4.01	18.02	21.13	27.92	8.07	23.10	12.90
Median	157.0	-0.5	178.5	4.7	154.7	-2.0	158.0	-2.0
Q1, Q3	149.3, 164.7	-3.3, 2.3	160.3, 188.3	-11.7, 20.0	128.7, 158.0	-6.7, 2.7	149.3, 187.0	-6.7, 11.3
Min, Max	149, 165	-3, 2	151, 190	-21, 29	125, 195	-7, 13	125, 195	-21, 29

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 2 Day 1, 1 Hour Post-Dose								
Nx	2	2	4	4	6	5	12	11
Mean	155.7	-1.8	172.7	2.5	125.7	-1.6	146.4	-0.2
SD	10.84	4.01	21.11	5.92	66.27	8.40	51.26	6.69
Median	155.7	-1.8	166.8	3.7	140.0	1.3	158.7	1.3
Q1, Q3	148.0, 163.3	-4.7, 1.0	160.3, 185.0	-2.0, 7.0	119.3, 163.3	-7.3, 2.0	137.7, 166.8	-5.3, 6.0
Min, Max	148, 163	-5, 1	154, 203	-5, 8	1, 191	-13, 9	1, 203	-13, 9
Cycle 3 Day 1, Pre-Dose								
Nx	0	0	4	4	3	3	7	7
Mean	NC	NC	179.0	8.8	155.3	-2.7	168.9	3.9
SD	NC	NC	34.59	23.59	36.90	14.74	34.82	19.71
Median	NC	NC	178.8	-0.3	146.0	-8.0	153.3	-5.3
Q1, Q3	NC, NC	NC, NC	149.3, 208.7	-6.3, 24.0	124.0, 196.0	-14.0, 14.0	145.3, 204.3	-8.0, 14.0
Min, Max	NC, NC	NC, NC	145, 213	-7, 43	124, 196	-14, 14	124, 213	-14, 43

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 3 Day 1, 1 Hour Post-Dose								
Nx	1	1	4	4	3	3	8	8
Mean	171.0	8.7	174.3	4.2	157.1	-0.9	167.5	2.8
SD	NC	NC	31.03	5.67	40.04	17.67	30.74	10.71
Median	171.0	8.7	162.8	3.0	146.7	-8.7	162.8	3.0
Q1, Q3	171.0, 171.0	8.7, 8.7	155.5, 193.2	-0.2, 8.5	123.3, 201.3	-13.3, 19.3	149.2, 186.2	-4.8, 10.2
Min, Max	171, 171	9, 9	152, 220	-1, 12	123, 201	-13, 19	123, 220	-13, 19
Cycle 5 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	185.0	9.0	177.3	9.6	181.2	9.3
SD	NC	NC	19.16	8.99	18.90	13.34	17.53	10.18
Median	NC	NC	176.0	13.3	184.0	10.0	180.0	11.7
Q1, Q3	NC, NC	NC, NC	172.0, 207.0	-1.3, 15.0	156.0, 192.0	-4.0, 22.7	172.0, 192.0	-1.3, 15.0
Min, Max	NC, NC	NC, NC	172, 207	-1, 15	156, 192	-4, 23	156, 207	-4, 23

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	2	2	3	3	5	5
Mean	NC	NC	199.5	16.0	172.7	4.9	183.4	9.3
SD	NC	NC	30.41	4.71	22.03	9.71	26.26	9.48
Median	NC	NC	199.5	16.0	162.0	0.7	178.0	12.7
Q1, Q3	NC, NC	NC, NC	178.0, 221.0	12.7, 19.3	158.0, 198.0	-2.0, 16.0	162.0, 198.0	0.7, 16.0
Min, Max	NC, NC	NC, NC	178, 221	13, 19	158, 198	-2, 16	158, 221	-2, 19
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	127.7	-45.6	173.5	2.5	146.0	-26.3
SD	NC	NC	45.76	74.96	24.75	9.19	42.78	59.36
Median	NC	NC	140.0	-12.7	173.5	2.5	156.0	-4.0
Q1, Q3	NC, NC	NC, NC	77.0, 166.0	-131.3, 7.3	156.0, 191.0	-4.0, 9.0	140.0, 166.0	-12.7, 7.3
Min, Max	NC, NC	NC, NC	77, 166	-131, 7	156, 191	-4, 9	77, 191	-131, 9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	1	5	4
Mean	NC	NC	173.0	-0.2	225.5	13.0	194.0	3.1
SD	NC	NC	21.70	8.88	43.13	NC	39.08	9.81
Median	NC	NC	162.0	3.3	225.5	13.0	195.0	4.8
Q1, Q3	NC, NC	NC, NC	159.0, 198.0	-10.3, 6.3	195.0, 256.0	13.0, 13.0	162.0, 198.0	-3.5, 9.7
Min, Max	NC, NC	NC, NC	159, 198	-10, 6	195, 256	13, 13	159, 256	-10, 13
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	1	3	2
Mean	NC	NC	159.0	6.3	222.0	2.0	201.0	4.2
SD	NC	NC	NC	NC	53.74	NC	52.60	3.06
Median	NC	NC	159.0	6.3	222.0	2.0	184.0	4.2
Q1, Q3	NC, NC	NC, NC	159.0, 159.0	6.3, 6.3	184.0, 260.0	2.0, 2.0	159.0, 260.0	2.0, 6.3
Min, Max	NC, NC	NC, NC	159, 159	6, 6	184, 260	2, 2	159, 260	2, 6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	155.0	2.3	190.0	8.0	172.5	5.2
SD	NC	NC	NC	NC	NC	NC	24.75	4.01
Median	NC	NC	155.0	2.3	190.0	8.0	172.5	5.2
Q1, Q3	NC, NC	NC, NC	155.0, 155.0	2.3, 2.3	190.0, 190.0	8.0, 8.0	155.0, 190.0	2.3, 8.0
Min, Max	NC, NC	NC, NC	155, 155	2, 2	190, 190	8, 8	155, 190	2, 8
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	154.0	1.3	182.0	0.0	168.0	0.7
SD	NC	NC	NC	NC	NC	NC	19.80	0.94
Median	NC	NC	154.0	1.3	182.0	0.0	168.0	0.7
Q1, Q3	NC, NC	NC, NC	154.0, 154.0	1.3, 1.3	182.0, 182.0	0.0, 0.0	154.0, 182.0	0.0, 1.3
Min, Max	NC, NC	NC, NC	154, 154	1, 1	182, 182	0, 0	154, 182	0, 1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	137.0	-15.7	186.0	4.0	161.5	-5.8
SD	NC	NC	NC	NC	NC	NC	34.65	13.91
Median	NC	NC	137.0	-15.7	186.0	4.0	161.5	-5.8
Q1, Q3	NC, NC	NC, NC	137.0, 137.0	-15.7, -15.7	186.0, 186.0	4.0, 4.0	137.0, 186.0	-15.7, 4.0
Min, Max	NC, NC	NC, NC	137, 137	-16, -16	186, 186	4, 4	137, 186	-16, 4
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	151.0	-1.7	NC	NC	151.0	-1.7
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	151.0	-1.7	NC	NC	151.0	-1.7
Q1, Q3	NC, NC	NC, NC	151.0, 151.0	-1.7, -1.7	NC, NC	NC, NC	151.0, 151.0	-1.7, -1.7
Min, Max	NC, NC	NC, NC	151, 151	-2, -2	NC, NC	NC, NC	151, 151	-2, -2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: PR Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	156.0	3.3	NC	NC	156.0	3.3
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	156.0	3.3	NC	NC	156.0	3.3
Q1, Q3	NC, NC	NC, NC	156.0, 156.0	3.3, 3.3	NC, NC	NC, NC	156.0, 156.0	3.3, 3.3
Min, Max	NC, NC	NC, NC	156, 156	3, 3	NC, NC	NC, NC	156, 156	3, 3
End of Treatment, Pre-Dose								
Nx	2	2	3	3	8	7	13	12
Mean	125.0	-19.7	166.0	8.6	167.5	-0.7	160.6	-1.5
SD	7.07	4.24	21.07	17.06	42.66	9.44	37.29	13.83
Median	125.0	-19.7	164.0	5.3	157.0	2.0	152.0	1.3
Q1, Q3	120.0, 130.0	-22.7, -16.7	146.0, 188.0	-6.7, 27.0	138.0, 179.0	-8.0, 4.0	134.0, 172.0	-12.3, 4.7
Min, Max	120, 130	-23, -17	146, 188	-7, 27	130, 262	-18, 11	120, 262	-23, 27

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	87.3		93.1		91.5		91.3	
SD	4.27		12.80		13.45		11.74	
Median	87.5		92.0		91.3		89.0	
Q1, Q3	84.0, 90.5		85.3, 106.0		84.0, 105.0		85.3, 96.0	
Min, Max	82, 92		74, 112		71, 109		71, 112	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	90.2	2.9	94.4	1.3	91.7	0.1	92.3	1.0
SD	6.85	3.71	15.07	3.35	14.19	2.91	12.98	3.22
Median	90.7	1.7	91.3	0.0	91.0	0.5	91.3	1.0
Q1, Q3	84.7, 95.7	0.7, 5.2	84.0, 113.0	-1.3, 4.7	79.3, 103.7	-2.0, 2.0	84.0, 97.3	-1.3, 2.0
Min, Max	82, 97	0, 8	75, 116	-2, 7	72, 113	-5, 5	72, 116	-5, 8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 2 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	87.3	0.0	94.2	1.1	92.1	0.6	91.9	0.7
SD	5.99	2.37	15.77	3.80	15.25	3.49	13.82	3.29
Median	88.3	-0.7	90.7	-0.3	90.8	0.0	90.7	0.0
Q1, Q3	82.3, 92.2	-1.7, 1.7	84.3, 114.0	-1.3, 4.7	81.3, 104.7	-0.7, 0.7	84.3, 95.7	-1.3, 0.7
Min, Max	80, 92	-2, 3	74, 116	-3, 8	72, 118	-3, 10	72, 118	-3, 10
Cycle 1 Day 1, 3 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	85.8	-1.5	94.2	1.1	91.1	-0.4	91.1	-0.1
SD	5.59	2.40	15.73	3.32	13.74	2.56	13.16	2.84
Median	86.7	-2.3	91.3	-0.3	90.3	0.3	90.0	-0.3
Q1, Q3	81.3, 90.2	-3.0, 0.0	83.3, 111.0	-0.7, 5.0	81.3, 103.7	-1.3, 1.3	83.3, 95.7	-2.0, 1.3
Min, Max	79, 91	-3, 2	73, 118	-2, 7	71, 110	-6, 2	71, 118	-6, 7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	84.1	-3.2	94.8	1.7	91.9	0.3	91.4	0.1
SD	4.83	2.27	15.92	4.15	14.96	4.13	13.97	4.08
Median	84.7	-3.7	90.7	0.7	88.3	-0.2	87.3	0.0
Q1, Q3	80.3, 87.8	-4.7, -1.7	82.7, 115.7	-1.3, 4.3	84.0, 103.7	-1.3, 1.3	82.7, 97.0	-1.3, 1.0
Min, Max	78, 89	-5, 0	75, 116	-3, 10	72, 119	-6, 11	72, 119	-6, 11
Cycle 1 Day 1, 6 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	85.3	-2.0	93.4	0.2	92.4	0.9	91.4	0.1
SD	4.57	0.94	13.43	2.34	13.87	1.80	12.38	2.10
Median	86.2	-2.3	90.0	0.7	92.2	0.2	89.3	0.0
Q1, Q3	81.7, 88.8	-2.7, -1.3	85.7, 103.7	-2.0, 1.3	82.7, 105.0	0.0, 2.0	84.0, 97.0	-1.3, 1.3
Min, Max	79, 89	-3, -1	75, 116	-2, 4	72, 112	-1, 4	72, 116	-3, 4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 8 Hours Post-Dose								
Nx	4	4	6	6	10	10	20	20
Mean	84.5	-2.8	95.1	0.9	91.8	0.3	91.3	-0.1
SD	7.86	3.70	14.77	1.95	14.08	1.79	13.24	2.56
Median	86.0	-1.5	96.2	0.3	91.7	0.2	90.3	0.0
Q1, Q3	78.7, 90.3	-5.3, -0.2	85.3, 107.7	0.0, 1.7	82.7, 103.3	-1.3, 2.0	83.0, 101.8	-1.3, 1.2
Min, Max	74, 92	-8, 0	73, 112	-1, 4	71, 112	-2, 3	71, 112	-8, 4
Cycle 1 Day 1, 12 Hours Post-Dose								
Nx	4	4	5	5	10	10	19	19
Mean	84.2	-3.1	95.3	1.5	91.1	-0.4	90.8	-0.5
SD	6.09	1.99	17.98	3.62	12.41	4.21	13.06	3.88
Median	85.3	-2.3	90.7	1.3	92.0	0.2	90.0	-1.0
Q1, Q3	79.7, 88.7	-4.3, -1.8	82.7, 111.3	-1.3, 5.0	81.3, 100.0	-2.7, 2.7	81.3, 100.0	-2.7, 2.7
Min, Max	76, 90	-6, -2	75, 117	-3, 5	72, 111	-8, 5	72, 117	-8, 5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 2, Pre-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	86.3	-0.9	95.9	2.8	90.9	-0.6	91.7	0.4
SD	7.35	3.14	15.58	3.85	13.70	3.55	13.33	3.80
Median	87.3	-0.2	94.0	2.0	89.3	0.3	89.3	0.7
Q1, Q3	81.0, 91.7	-3.0, 1.2	84.0, 114.7	1.0, 6.7	82.0, 105.0	-2.0, 1.3	84.0, 97.0	-0.7, 2.0
Min, Max	77, 94	-5, 2	77, 118	-3, 9	71, 111	-9, 3	71, 118	-9, 9
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	8	8	17	17
Mean	86.8	1.1	94.4	1.1	92.2	2.3	92.0	1.7
SD	6.26	2.78	16.85	6.41	19.07	8.09	16.13	6.55
Median	88.0	2.0	91.7	-0.3	90.5	0.0	88.7	0.0
Q1, Q3	80.0, 92.3	-2.0, 3.3	82.0, 107.3	-3.3, 1.7	77.7, 100.5	-2.3, 3.0	80.0, 97.7	-2.0, 2.0
Min, Max	80, 92	-2, 3	75, 119	-4, 13	70, 130	-4, 21	70, 130	-4, 21

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 1 Hour Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	86.3	0.7	94.3	0.9	96.3	4.4	93.9	2.6
SD	6.81	3.46	14.24	2.44	22.02	11.53	17.50	8.31
Median	88.7	2.7	92.2	1.3	91.3	-0.7	90.0	0.7
Q1, Q3	78.7, 91.7	-3.3, 2.7	82.0, 107.7	0.3, 2.0	80.7, 105.3	-2.7, 4.0	80.7, 105.3	-2.7, 2.7
Min, Max	79, 92	-3, 3	78, 114	-3, 4	71, 134	-4, 29	71, 134	-4, 29
Cycle 1 Day 6, 2 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	86.6	0.9	93.5	0.2	94.7	2.8	92.9	1.6
SD	6.20	2.69	16.20	3.17	18.49	7.50	15.86	5.65
Median	87.3	1.3	91.0	0.5	92.3	0.7	90.5	0.8
Q1, Q3	80.0, 92.3	-2.0, 3.3	82.0, 107.0	-1.3, 2.0	80.7, 106.3	-1.3, 4.0	80.7, 106.3	-1.3, 3.3
Min, Max	80, 92	-2, 3	74, 116	-5, 4	73, 130	-3, 21	73, 130	-5, 21

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 3 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	86.4	0.8	92.6	-0.8	94.1	2.3	92.3	1.0
SD	6.48	3.02	15.31	2.96	16.37	6.10	14.41	4.82
Median	88.0	2.0	89.0	-1.0	94.3	0.7	90.3	0.3
Q1, Q3	79.3, 92.0	-2.7, 3.0	81.7, 105.3	-2.0, 1.3	83.3, 104.0	-0.7, 2.0	81.7, 104.0	-1.3, 2.0
Min, Max	79, 92	-3, 3	75, 115	-5, 3	74, 126	-4, 17	74, 126	-5, 17
Cycle 1 Day 6, 4 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	85.4	-0.2	93.8	0.5	93.9	2.0	92.4	1.1
SD	6.17	2.69	16.32	4.31	16.14	5.97	14.69	4.89
Median	85.3	-0.7	88.7	-0.5	95.3	0.3	89.8	-0.2
Q1, Q3	79.3, 91.7	-2.7, 2.7	82.0, 107.3	-3.3, 3.3	86.0, 103.3	-0.7, 2.0	82.0, 103.3	-2.3, 2.7
Min, Max	79, 92	-3, 3	77, 119	-3, 7	71, 125	-5, 16	71, 125	-5, 16

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 6 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	88.0	2.3	93.4	0.1	93.3	1.5	92.5	1.2
SD	3.71	0.88	16.94	5.12	14.72	5.33	13.87	4.68
Median	87.3	2.7	89.0	1.3	91.0	0.3	89.5	1.7
Q1, Q3	84.7, 92.0	1.3, 3.0	79.0, 112.3	-3.3, 3.0	83.3, 102.7	-0.7, 3.0	82.0, 102.7	-0.7, 3.0
Min, Max	85, 92	1, 3	77, 115	-8, 6	74, 121	-5, 12	74, 121	-8, 12
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	85.3	-0.3	101.4	4.5	90.4	-3.3	92.6	-0.2
SD	6.77	3.28	19.72	4.96	11.35	3.52	14.15	5.02
Median	86.7	0.7	106.3	2.7	90.2	-1.7	91.3	0.0
Q1, Q3	78.0, 91.3	-4.0, 2.3	86.2, 116.7	1.2, 7.8	87.3, 99.3	-6.7, -1.0	86.7, 99.3	-2.0, 1.3
Min, Max	78, 91	-4, 2	75, 118	1, 12	71, 104	-9, 0	71, 118	-9, 12

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	86.8	1.1	101.8	4.8	91.4	-2.2	93.5	0.7
SD	3.56	1.39	19.27	5.29	12.11	3.54	13.86	4.75
Median	88.7	0.7	105.8	4.0	92.7	-1.3	89.7	0.3
Q1, Q3	82.7, 89.0	0.0, 2.7	86.3, 117.2	1.3, 8.3	86.0, 100.7	-5.3, 0.3	86.0, 100.7	-0.7, 2.7
Min, Max	83, 89	0, 3	77, 118	-1, 12	71, 105	-7, 2	71, 118	-7, 12
Cycle 1 Day 14, 2 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	85.4	-0.2	101.4	4.5	91.7	-2.0	93.2	0.4
SD	5.60	2.14	17.73	3.42	10.99	3.63	13.15	4.21
Median	86.7	0.7	106.2	3.7	91.5	-2.3	90.3	0.7
Q1, Q3	79.3, 90.3	-2.7, 1.3	87.7, 115.2	2.3, 6.7	84.7, 102.7	-5.3, -0.7	84.7, 102.7	-2.7, 3.3
Min, Max	79, 90	-3, 1	78, 115	1, 9	75, 104	-5, 4	75, 115	-5, 9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 14, 3 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	86.2	0.6	99.3	2.3	91.9	-1.7	92.9	0.1
SD	6.84	3.40	16.65	1.66	11.64	3.98	12.60	3.55
Median	88.0	2.0	102.2	2.8	94.3	-0.7	93.0	1.7
Q1, Q3	78.7, 92.0	-3.3, 3.0	86.7, 111.8	1.2, 3.5	84.0, 100.0	-4.7, 1.7	84.0, 100.0	-2.0, 2.3
Min, Max	79, 92	-3, 3	77, 115	0, 4	73, 106	-8, 2	73, 115	-8, 4
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	85.8	0.1	99.6	2.7	91.9	-1.8	92.8	0.0
SD	6.30	2.99	18.77	3.58	11.51	5.16	13.34	4.44
Median	88.0	1.7	101.7	1.2	93.5	-3.0	90.7	1.0
Q1, Q3	78.7, 90.7	-3.3, 2.0	85.8, 113.3	0.7, 4.7	80.7, 103.0	-5.3, 3.3	80.7, 103.0	-3.3, 2.0
Min, Max	79, 91	-3, 2	75, 120	0, 8	77, 104	-8, 5	75, 120	-8, 8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 14, 6 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	86.9	1.2	100.3	3.4	93.1	-0.6	93.9	1.1
SD	6.68	3.37	18.82	3.43	12.87	3.48	13.84	3.61
Median	89.3	3.0	105.2	2.7	94.2	0.0	92.0	1.3
Q1, Q3	79.3, 92.0	-2.7, 3.3	85.8, 114.8	0.8, 6.0	82.7, 104.3	-3.0, 2.3	82.7, 104.3	-0.7, 3.3
Min, Max	79, 92	-3, 3	75, 116	0, 8	75, 109	-6, 3	75, 116	-6, 8
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	6	6	12	12
Mean	83.8	-1.7	98.4	1.5	89.8	0.6	91.7	0.5
SD	6.36	1.41	15.74	2.44	19.29	9.10	16.43	6.38
Median	83.8	-1.7	103.5	1.8	85.3	-0.7	88.8	-0.0
Q1, Q3	79.3, 88.3	-2.7, -0.7	86.8, 110.0	-0.3, 3.3	77.3, 92.0	-6.7, 1.3	78.3, 103.5	-2.3, 2.0
Min, Max	79, 88	-3, -1	77, 110	-2, 4	73, 126	-7, 18	73, 126	-7, 18

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 2 Day 1, 1 Hour Post-Dose								
Nx	2	2	4	4	6	6	12	12
Mean	85.3	-0.2	97.9	1.0	90.7	1.5	92.2	1.1
SD	6.60	1.65	17.32	2.26	16.12	5.11	15.02	3.73
Median	85.3	-0.2	103.3	0.2	87.7	1.3	90.7	0.5
Q1, Q3	80.7, 90.0	-1.3, 1.0	85.2, 110.7	-0.3, 2.3	82.0, 96.0	-2.0, 2.7	81.3, 103.3	-1.0, 2.3
Min, Max	81, 90	-1, 1	74, 111	-1, 4	72, 119	-5, 10	72, 119	-5, 10
Cycle 3 Day 1, Pre-Dose								
Nx	0	0	4	4	4	4	8	8
Mean	NC	NC	100.3	3.4	93.6	2.9	97.0	3.2
SD	NC	NC	18.19	4.99	16.16	4.66	16.33	4.48
Median	NC	NC	104.0	1.7	92.3	4.8	97.8	3.5
Q1, Q3	NC, NC	NC, NC	86.2, 114.5	0.2, 6.7	80.7, 106.5	0.2, 5.7	80.7, 112.7	0.2, 5.7
Min, Max	NC, NC	NC, NC	77, 117	-0, 11	77, 113	-4, 6	77, 117	-4, 11

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 3 Day 1, 1 Hour Post-Dose								
Nx	1	1	4	4	4	4	9	9
Mean	91.3	2.3	99.6	2.7	92.5	1.8	95.5	2.3
SD	NC	NC	17.98	2.39	17.99	6.24	16.05	4.11
Median	91.3	2.3	102.3	2.2	89.7	4.0	96.3	2.3
Q1, Q3	91.3, 91.3	2.3, 2.3	86.2, 113.0	1.2, 4.2	78.3, 106.7	-1.7, 5.3	81.3, 108.3	2.0, 4.0
Min, Max	91, 91	2, 2	76, 118	0, 6	75, 115	-7, 7	75, 118	-7, 7
Cycle 5 Day 1, Pre-Dose								
Nx	0	0	3	3	4	4	7	7
Mean	NC	NC	101.0	3.8	93.5	4.0	96.7	3.9
SD	NC	NC	23.43	5.43	23.73	8.52	21.92	6.79
Median	NC	NC	113.0	1.3	89.5	0.8	97.0	1.3
Q1, Q3	NC, NC	NC, NC	74.0, 116.0	0.0, 10.0	76.0, 111.0	-1.7, 9.7	74.0, 116.0	-1.3, 10.0
Min, Max	NC, NC	NC, NC	74, 116	0, 10	70, 125	-2, 16	70, 125	-2, 16

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	2	2	4	4	6	6
Mean	NC	NC	96.5	3.7	94.5	5.0	95.2	4.6
SD	NC	NC	23.33	3.30	21.67	6.87	19.79	5.56
Median	NC	NC	96.5	3.7	90.5	3.8	90.5	3.8
Q1, Q3	NC, NC	NC, NC	80.0, 113.0	1.3, 6.0	78.0, 111.0	0.3, 9.7	80.0, 113.0	1.3, 6.0
Min, Max	NC, NC	NC, NC	80, 113	1, 6	74, 123	-2, 14	74, 123	-2, 14
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	94.7	0.8	93.3	2.0	94.0	1.4
SD	NC	NC	16.50	2.80	25.50	7.31	19.22	5.00
Median	NC	NC	95.0	-0.7	93.0	-1.0	94.0	-0.8
Q1, Q3	NC, NC	NC, NC	78.0, 111.0	-1.0, 4.0	68.0, 119.0	-3.3, 10.3	78.0, 111.0	-1.0, 4.0
Min, Max	NC, NC	NC, NC	78, 111	-1, 4	68, 119	-3, 10	68, 119	-3, 10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	94.7	0.8	114.0	12.7	102.4	5.5
SD	NC	NC	21.01	3.24	28.28	17.91	23.08	11.31
Median	NC	NC	94.0	0.0	114.0	12.7	94.0	0.0
Q1, Q3	NC, NC	NC, NC	74.0, 116.0	-2.0, 4.3	94.0, 134.0	0.0, 25.3	94.0, 116.0	0.0, 4.3
Min, Max	NC, NC	NC, NC	74, 116	-2, 4	94, 134	0, 25	74, 134	-2, 25
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	94.0	-2.0	117.0	15.7	109.3	9.8
SD	NC	NC	NC	NC	28.28	17.91	24.01	16.26
Median	NC	NC	94.0	-2.0	117.0	15.7	97.0	3.0
Q1, Q3	NC, NC	NC, NC	94.0, 94.0	-2.0, -2.0	97.0, 137.0	3.0, 28.3	94.0, 137.0	-2.0, 28.3
Min, Max	NC, NC	NC, NC	94, 94	-2, -2	97, 137	3, 28	94, 137	-2, 28

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	96.0	0.0	94.0	0.0	95.0	0.0
SD	NC	NC	NC	NC	NC	NC	1.41	0.00
Median	NC	NC	96.0	0.0	94.0	0.0	95.0	0.0
Q1, Q3	NC, NC	NC, NC	96.0, 96.0	0.0, 0.0	94.0, 94.0	0.0, 0.0	94.0, 96.0	0.0, 0.0
Min, Max	NC, NC	NC, NC	96, 96	0, 0	94, 94	0, 0	94, 96	0, 0
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	96.0	0.0	94.0	0.0	95.0	0.0
SD	NC	NC	NC	NC	NC	NC	1.41	0.00
Median	NC	NC	96.0	0.0	94.0	0.0	95.0	0.0
Q1, Q3	NC, NC	NC, NC	96.0, 96.0	0.0, 0.0	94.0, 94.0	0.0, 0.0	94.0, 96.0	0.0, 0.0
Min, Max	NC, NC	NC, NC	96, 96	0, 0	94, 94	0, 0	94, 96	0, 0

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	95.0	-1.0	99.0	5.0	97.0	2.0
SD	NC	NC	NC	NC	NC	NC	2.83	4.24
Median	NC	NC	95.0	-1.0	99.0	5.0	97.0	2.0
Q1, Q3	NC, NC	NC, NC	95.0, 95.0	-1.0, -1.0	99.0, 99.0	5.0, 5.0	95.0, 99.0	-1.0, 5.0
Min, Max	NC, NC	NC, NC	95, 95	-1, -1	99, 99	5, 5	95, 99	-1, 5
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	94.0	-2.0	NC	NC	94.0	-2.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	94.0	-2.0	NC	NC	94.0	-2.0
Q1, Q3	NC, NC	NC, NC	94.0, 94.0	-2.0, -2.0	NC, NC	NC, NC	94.0, 94.0	-2.0, -2.0
Min, Max	NC, NC	NC, NC	94, 94	-2, -2	NC, NC	NC, NC	94, 94	-2, -2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QRS Duration, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	93.0	-3.0	NC	NC	93.0	-3.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	93.0	-3.0	NC	NC	93.0	-3.0
Q1, Q3	NC, NC	NC, NC	93.0, 93.0	-3.0, -3.0	NC, NC	NC, NC	93.0, 93.0	-3.0, -3.0
Min, Max	NC, NC	NC, NC	93, 93	-3, -3	NC, NC	NC, NC	93, 93	-3, -3
End of Treatment, Pre-Dose								
Nx	2	2	3	3	8	8	13	13
Mean	82.0	-2.0	96.0	4.0	95.3	3.0	93.4	2.4
SD	2.83	0.00	10.82	5.57	17.14	9.89	14.74	8.14
Median	82.0	-2.0	99.0	3.0	91.0	1.3	90.0	1.3
Q1, Q3	80.0, 84.0	-2.0, -2.0	84.0, 105.0	-1.0, 10.0	85.0, 99.5	-3.5, 5.8	84.0, 99.0	-2.0, 5.0
Min, Max	80, 84	-2, -2	84, 105	-1, 10	78, 133	-8, 24	78, 133	-8, 24

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	399.6		379.9		376.0		381.8	
SD	44.77		38.29		29.23		34.73	
Median	417.7		395.0		378.3		385.7	
Q1, Q3	372.7, 426.5		354.7, 407.0		360.3, 393.3		360.3, 407.0	
Min, Max	333, 430		311, 425		317, 426		311, 430	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	392.5	-7.1	384.2	4.3	378.9	2.9	383.2	1.4
SD	29.87	18.78	46.97	12.48	42.53	17.08	40.45	15.79
Median	404.0	-9.5	396.7	6.3	384.8	7.2	390.7	6.3
Q1, Q3	373.7, 411.3	-22.5, 8.3	358.7, 426.0	-9.7, 18.3	371.3, 407.3	4.0, 12.7	364.0, 411.3	-8.0, 12.7
Min, Max	349, 413	-25, 15	299, 431	-12, 19	276, 433	-41, 18	276, 433	-41, 19

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 1, 2 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	396.8	-2.8	381.4	1.5	387.4	11.4	387.2	5.4
SD	44.07	15.59	36.52	8.98	24.68	12.78	31.56	13.07
Median	404.7	2.7	400.7	-1.3	382.2	6.8	385.7	2.7
Q1, Q3	363.0, 430.7	-13.0, 7.5	353.3, 413.0	-6.3, 8.0	366.7, 415.3	0.7, 22.0	364.7, 415.3	-0.7, 9.0
Min, Max	339, 439	-25, 9	319, 418	-7, 18	355, 428	-1, 37	319, 439	-25, 37
Cycle 1 Day 1, 3 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	383.6	-16.0	384.7	4.8	375.0	-1.0	379.8	-2.0
SD	42.26	24.75	38.81	10.24	43.88	21.38	40.11	19.61
Median	388.8	-7.3	398.0	6.3	378.0	0.7	383.3	0.0
Q1, Q3	348.0, 419.2	-32.0, 0.0	362.0, 416.0	0.0, 9.0	370.7, 408.7	-6.7, 8.7	362.0, 413.7	-6.7, 8.7
Min, Max	336, 421	-52, 3	311, 417	-11, 22	268, 427	-49, 33	268, 427	-52, 33

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	374.8	-24.8	379.2	-0.7	380.5	4.5	379.0	-2.8
SD	41.24	17.71	39.06	9.02	38.71	15.48	37.30	17.44
Median	381.0	-25.8	399.3	1.3	377.2	-0.8	379.3	-2.0
Q1, Q3	345.3, 404.3	-39.8, -9.7	359.3, 408.0	-8.7, 4.7	360.0, 421.3	-4.7, 11.3	360.0, 408.0	-8.7, 4.0
Min, Max	320, 417	-41, -6	303, 409	-16, 11	301, 429	-16, 33	301, 429	-41, 33
Cycle 1 Day 1, 6 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	366.7	-32.9	378.0	-2.0	377.8	1.8	375.7	-6.0
SD	50.85	28.83	32.76	12.21	44.01	22.13	40.02	23.90
Median	366.0	-36.5	396.7	-1.3	383.3	2.7	382.7	-0.7
Q1, Q3	328.3, 405.0	-54.8, -11.0	342.7, 403.7	-12.0, 8.7	366.7, 405.3	-6.0, 5.7	358.0, 403.7	-12.0, 5.7
Min, Max	307, 427	-63, 4	323, 404	-21, 11	271, 431	-46, 38	271, 431	-63, 38

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 8 Hours Post-Dose								
Nx	4	4	6	6	10	10	20	20
Mean	367.5	-32.1	381.5	-0.3	377.9	1.9	376.9	-5.6
SD	37.55	10.58	46.76	8.39	25.29	8.90	33.57	16.11
Median	384.3	-30.0	397.5	1.5	375.8	3.2	381.5	-1.5
Q1, Q3	347.3, 387.7	-39.8, -24.3	362.0, 412.7	-2.7, 5.7	369.3, 401.3	-6.0, 10.0	365.7, 400.5	-14.0, 6.5
Min, Max	311, 390	-46, -22	296, 423	-15, 7	329, 417	-13, 11	296, 423	-46, 11
Cycle 1 Day 1, 12 Hours Post-Dose								
Nx	4	4	5	5	10	10	19	19
Mean	376.4	-23.2	371.5	-7.7	380.7	4.7	377.4	-4.4
SD	43.04	20.59	51.10	9.15	22.94	21.26	34.18	21.05
Median	380.8	-22.3	390.3	-2.7	379.3	4.8	379.3	-1.3
Q1, Q3	343.7, 409.2	-40.0, -6.3	352.0, 398.0	-16.7, -0.7	363.3, 382.0	-2.7, 19.0	358.0, 398.0	-18.7, 5.7
Min, Max	322, 422	-47, -1	293, 424	-19, 0	356, 433	-29, 46	293, 433	-47, 46

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 2, Pre-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	382.0	-17.6	375.5	-4.4	369.8	-6.2	374.0	-7.7
SD	37.32	10.18	34.77	9.44	35.33	17.51	33.99	14.31
Median	394.7	-16.8	383.3	-5.7	370.8	-0.3	379.7	-6.0
Q1, Q3	360.0, 404.0	-24.5, -10.7	348.0, 390.7	-14.7, 4.7	352.7, 390.7	-12.3, 5.7	352.7, 392.7	-15.3, 4.7
Min, Max	327, 411	-31, -6	321, 430	-16, 9	295, 432	-47, 9	295, 432	-47, 9
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	8	8	17	17
Mean	388.4	-3.2	380.8	-3.3	370.0	-5.6	377.1	-4.4
SD	47.00	25.57	43.95	8.71	56.45	40.12	48.26	28.48
Median	379.3	9.7	394.8	-6.3	371.7	1.5	379.3	0.3
Q1, Q3	346.7, 439.3	-32.7, 13.3	358.3, 415.0	-10.0, 0.7	341.7, 386.3	-9.7, 5.8	358.3, 395.7	-10.0, 7.0
Min, Max	347, 439	-33, 13	303, 419	-10, 12	282, 478	-92, 52	282, 478	-92, 52

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 1 Hour Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	409.0	17.3	386.3	2.2	375.7	-1.8	384.8	2.7
SD	50.20	3.46	39.91	6.79	47.78	24.67	44.57	18.71
Median	425.3	19.3	395.0	5.7	375.0	-5.3	388.0	5.7
Q1, Q3	352.7, 449.0	13.3, 19.3	366.7, 412.7	-1.7, 6.7	360.7, 388.0	-9.3, 6.0	360.7, 412.7	-8.3, 13.3
Min, Max	353, 449	13, 19	318, 431	-10, 7	293, 474	-39, 48	293, 474	-39, 48
Cycle 1 Day 6, 2 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	390.2	-1.4	381.6	-2.5	377.2	-0.3	380.9	-1.2
SD	51.97	12.53	36.25	19.96	53.95	27.41	45.79	22.14
Median	396.7	2.0	382.2	-4.3	382.0	-4.0	383.3	-3.8
Q1, Q3	335.3, 438.7	-15.3, 9.0	355.7, 395.0	-12.7, 15.0	368.0, 393.3	-6.7, 0.0	355.7, 395.0	-12.7, 9.0
Min, Max	335, 439	-15, 9	335, 440	-32, 23	270, 480	-47, 54	270, 480	-47, 54

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 3 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	376.1	-15.6	379.4	-4.7	379.3	1.8	378.8	-3.3
SD	43.86	16.55	41.75	15.33	46.39	19.29	41.87	17.81
Median	378.0	-10.7	384.8	-1.2	371.3	-0.7	378.8	-2.7
Q1, Q3	331.3, 419.0	-34.0, -2.0	350.7, 400.7	-17.7, 6.0	367.3, 396.0	-12.0, 2.7	350.7, 400.7	-14.0, 2.7
Min, Max	331, 419	-34, -2	317, 438	-27, 13	303, 475	-14, 49	303, 475	-34, 49
Cycle 1 Day 6, 4 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	376.6	-15.1	377.4	-6.7	373.3	-4.2	375.2	-6.9
SD	43.32	12.37	39.72	7.78	36.13	16.86	36.10	13.61
Median	384.0	-14.0	387.7	-7.3	377.3	0.7	383.3	-4.3
Q1, Q3	330.0, 415.7	-28.0, -3.3	356.3, 392.7	-12.0, 0.0	361.7, 392.7	-13.0, 7.0	359.3, 392.7	-14.0, 1.0
Min, Max	330, 416	-28, -3	311, 429	-17, 4	297, 427	-38, 17	297, 429	-38, 17

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 6 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	378.7	-13.0	374.3	-9.8	372.6	-5.0	374.2	-7.9
SD	46.51	7.75	44.35	6.60	35.23	13.44	37.71	10.74
Median	390.7	-11.7	390.8	-10.0	369.3	-9.0	378.5	-9.7
Q1, Q3	327.3, 418.0	-21.3, -6.0	350.0, 393.3	-14.3, -4.7	364.3, 380.3	-13.3, 0.0	358.7, 393.3	-14.3, -2.0
Min, Max	327, 418	-21, -6	297, 423	-18, -2	302, 435	-24, 20	297, 435	-24, 20
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	394.0	2.3	410.8	4.6	372.1	-4.2	389.1	0.0
SD	51.44	6.56	7.31	17.53	16.09	8.70	29.49	11.52
Median	421.3	1.3	412.5	4.8	378.7	-4.2	387.3	-2.7
Q1, Q3	334.7, 426.0	-3.7, 9.3	405.8, 415.8	-10.2, 19.3	365.3, 380.0	-6.0, 3.3	378.0, 414.0	-6.0, 5.0
Min, Max	335, 426	-4, 9	401, 418	-14, 23	343, 387	-19, 5	335, 426	-19, 23

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	379.8	-11.9	412.1	5.8	379.0	2.7	389.4	0.3
SD	35.79	15.56	9.95	5.98	19.54	12.50	25.42	12.83
Median	392.7	-19.3	407.3	5.7	384.5	5.5	392.7	3.7
Q1, Q3	339.3, 407.3	-22.3, 6.0	407.0, 417.2	0.8, 10.8	365.7, 391.3	-9.0, 9.3	379.7, 407.3	-9.0, 9.3
Min, Max	339, 407	-22, 6	407, 427	-0, 12	347, 401	-15, 19	339, 427	-22, 19
Cycle 1 Day 14, 2 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	380.4	-11.2	409.8	3.6	380.2	3.8	389.4	0.3
SD	37.69	19.36	19.64	16.13	16.29	14.10	25.41	15.92
Median	382.0	-12.3	409.0	9.8	382.3	-0.7	386.7	-0.7
Q1, Q3	342.0, 417.3	-30.0, 8.7	397.3, 422.3	-5.3, 12.5	374.0, 391.0	-2.3, 6.0	381.3, 408.0	-10.0, 9.7
Min, Max	342, 417	-30, 9	387, 435	-20, 15	352, 399	-10, 31	342, 435	-30, 31

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 14, 3 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	376.9	-14.8	409.2	2.9	382.4	6.1	389.4	0.3
SD	45.69	10.22	18.89	13.30	19.88	19.30	28.21	17.10
Median	386.0	-12.3	405.3	7.5	388.7	1.7	390.7	1.7
Q1, Q3	327.3, 417.3	-26.0, -6.0	396.7, 421.7	-5.8, 11.7	376.3, 394.7	-3.3, 12.7	386.0, 402.7	-12.3, 10.3
Min, Max	327, 417	-26, -6	391, 435	-16, 13	345, 401	-17, 40	327, 435	-26, 40
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	381.8	-9.9	414.8	8.6	378.9	2.6	390.6	1.6
SD	54.73	21.32	18.23	14.49	15.77	17.31	31.13	17.40
Median	378.7	-4.7	413.5	15.0	383.3	-0.8	388.7	0.3
Q1, Q3	328.7, 438.0	-33.3, 8.3	402.8, 426.8	0.2, 17.0	372.7, 388.7	-11.3, 6.7	378.7, 411.7	-11.3, 13.3
Min, Max	329, 438	-33, 8	394, 438	-13, 17	351, 395	-13, 35	329, 438	-33, 35

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 6 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	376.6	-15.1	407.7	1.4	382.2	5.9	388.7	-0.3
SD	32.15	20.06	13.36	10.08	14.52	15.80	21.97	16.48
Median	384.0	-25.3	405.2	4.5	386.7	2.3	390.0	2.0
Q1, Q3	341.3, 404.3	-28.0, 8.0	398.7, 416.7	-5.8, 8.7	376.7, 390.0	-4.7, 4.3	384.0, 403.0	-6.0, 8.0
Min, Max	341, 404	-28, 8	394, 426	-13, 9	356, 397	-6, 37	341, 426	-28, 37
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	6	6	12	12
Mean	402.7	-18.2	405.2	-1.1	393.4	11.9	398.9	2.6
SD	16.03	3.54	14.17	25.78	28.13	13.00	21.71	19.74
Median	402.7	-18.2	406.8	5.8	396.0	10.2	399.3	6.2
Q1, Q3	391.3, 414.0	-20.7, -15.7	394.5, 415.8	-16.7, 14.5	368.0, 405.3	5.3, 14.7	389.2, 412.8	-9.8, 12.8
Min, Max	391, 414	-21, -16	387, 420	-38, 22	358, 437	-4, 35	358, 437	-38, 35

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 2 Day 1, 1 Hour Post-Dose								
Nx	2	2	4	4	6	6	12	12
Mean	421.3	0.5	399.8	-6.4	389.5	8.0	398.3	1.9
SD	11.31	1.18	11.64	24.51	26.36	21.38	22.45	20.44
Median	421.3	0.5	401.7	0.7	392.7	2.2	401.7	0.5
Q1, Q3	413.3, 429.3	-0.3, 1.3	392.5, 407.2	-23.5, 10.7	365.3, 409.3	-6.7, 10.0	388.0, 412.7	-6.3, 8.7
Min, Max	413, 429	-0, 1	384, 412	-41, 14	353, 424	-9, 49	353, 429	-41, 49
Cycle 3 Day 1, Pre-Dose								
Nx	0	0	4	4	4	4	8	8
Mean	NC	NC	414.5	8.3	393.5	10.9	404.0	9.6
SD	NC	NC	20.39	10.31	20.69	23.98	22.08	17.15
Median	NC	NC	409.7	8.7	400.2	9.3	404.8	8.7
Q1, Q3	NC, NC	NC, NC	402.0, 427.0	-0.5, 17.0	381.3, 405.7	-7.2, 29.0	397.3, 410.5	-0.7, 17.8
Min, Max	NC, NC	NC, NC	395, 443	-3, 18	363, 410	-16, 41	363, 443	-16, 41

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 3 Day 1, 1 Hour Post-Dose								
Nx	1	1	4	4	4	4	9	9
Mean	412.3	-17.3	420.9	14.7	393.5	10.9	407.8	9.4
SD	NC	NC	25.97	16.01	22.59	21.71	25.20	19.42
Median	412.3	-17.3	412.7	12.3	396.8	5.7	407.7	2.0
Q1, Q3	412.3, 412.3	-17.3, -17.3	403.8, 438.0	1.3, 28.0	377.7, 409.3	-3.8, 25.7	400.0, 417.0	0.7, 22.7
Min, Max	412, 412	-17, -17	400, 458	1, 33	363, 417	-9, 41	363, 458	-17, 41
Cycle 5 Day 1, Pre-Dose								
Nx	0	0	3	3	4	4	7	7
Mean	NC	NC	418.3	8.3	383.3	-8.8	398.3	-1.5
SD	NC	NC	19.09	5.86	16.84	30.87	24.80	23.92
Median	NC	NC	411.0	6.0	378.5	5.0	404.0	6.0
Q1, Q3	NC, NC	NC, NC	404.0, 440.0	4.0, 15.0	370.5, 396.0	-25.5, 7.8	371.0, 411.0	4.0, 9.7
Min, Max	NC, NC	NC, NC	404, 440	4, 15	370, 406	-55, 10	370, 440	-55, 15

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	2	2	4	4	6	6
Mean	NC	NC	416.5	5.0	385.5	-6.6	395.8	-2.7
SD	NC	NC	12.02	7.07	31.56	31.61	29.71	25.40
Median	NC	NC	416.5	5.0	394.5	-9.5	401.5	-3.0
Q1, Q3	NC, NC	NC, NC	408.0, 425.0	0.0, 10.0	367.0, 404.0	-27.5, 14.3	394.0, 413.0	-13.0, 10.0
Min, Max	NC, NC	NC, NC	408, 425	0, 10	340, 413	-42, 35	340, 425	-42, 35
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	412.3	6.3	406.0	16.6	409.2	11.4
SD	NC	NC	17.62	15.31	44.71	30.70	30.59	22.41
Median	NC	NC	422.0	-2.0	401.0	27.0	411.5	11.0
Q1, Q3	NC, NC	NC, NC	392.0, 423.0	-3.0, 24.0	364.0, 453.0	-18.0, 40.7	392.0, 423.0	-3.0, 27.0
Min, Max	NC, NC	NC, NC	392, 423	-3, 24	364, 453	-18, 41	364, 453	-18, 41

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	403.3	-2.7	421.0	27.8	410.4	9.5
SD	NC	NC	2.31	14.22	36.77	9.66	20.84	20.09
Median	NC	NC	402.0	4.0	421.0	27.8	402.0	7.0
Q1, Q3	NC, NC	NC, NC	402.0, 406.0	-19.0, 7.0	395.0, 447.0	21.0, 34.7	402.0, 406.0	4.0, 21.0
Min, Max	NC, NC	NC, NC	402, 406	-19, 7	395, 447	21, 35	395, 447	-19, 35
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	395.0	0.0	423.5	30.3	414.0	20.2
SD	NC	NC	NC	NC	30.41	16.03	27.07	20.86
Median	NC	NC	395.0	0.0	423.5	30.3	402.0	19.0
Q1, Q3	NC, NC	NC, NC	395.0, 395.0	0.0, 0.0	402.0, 445.0	19.0, 41.7	395.0, 445.0	0.0, 41.7
Min, Max	NC, NC	NC, NC	395, 395	0, 0	402, 445	19, 42	395, 445	0, 42

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	394.0	-1.0	392.0	31.7	393.0	15.3
SD	NC	NC	NC	NC	NC	NC	1.41	23.10
Median	NC	NC	394.0	-1.0	392.0	31.7	393.0	15.3
Q1, Q3	NC, NC	NC, NC	394.0, 394.0	-1.0, -1.0	392.0, 392.0	31.7, 31.7	392.0, 394.0	-1.0, 31.7
Min, Max	NC, NC	NC, NC	394, 394	-1, -1	392, 392	32, 32	392, 394	-1, 32
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	412.0	17.0	388.0	27.7	400.0	22.3
SD	NC	NC	NC	NC	NC	NC	16.97	7.54
Median	NC	NC	412.0	17.0	388.0	27.7	400.0	22.3
Q1, Q3	NC, NC	NC, NC	412.0, 412.0	17.0, 17.0	388.0, 388.0	27.7, 27.7	388.0, 412.0	17.0, 27.7
Min, Max	NC, NC	NC, NC	412, 412	17, 17	388, 388	28, 28	388, 412	17, 28

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	386.0	-9.0	377.0	16.7	381.5	3.8
SD	NC	NC	NC	NC	NC	NC	6.36	18.15
Median	NC	NC	386.0	-9.0	377.0	16.7	381.5	3.8
Q1, Q3	NC, NC	NC, NC	386.0, 386.0	-9.0, -9.0	377.0, 377.0	16.7, 16.7	377.0, 386.0	-9.0, 16.7
Min, Max	NC, NC	NC, NC	386, 386	-9, -9	377, 377	17, 17	377, 386	-9, 17
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	385.0	-10.0	NC	NC	385.0	-10.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	385.0	-10.0	NC	NC	385.0	-10.0
Q1, Q3	NC, NC	NC, NC	385.0, 385.0	-10.0, -10.0	NC, NC	NC, NC	385.0, 385.0	-10.0, -10.0
Min, Max	NC, NC	NC, NC	385, 385	-10, -10	NC, NC	NC, NC	385, 385	-10, -10

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QT Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	396.0	1.0	NC	NC	396.0	1.0
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	396.0	1.0	NC	NC	396.0	1.0
Q1, Q3	NC, NC	NC, NC	396.0, 396.0	1.0, 1.0	NC, NC	NC, NC	396.0, 396.0	1.0, 1.0
Min, Max	NC, NC	NC, NC	396, 396	1, 1	NC, NC	NC, NC	396, 396	1, 1
End of Treatment, Pre-Dose								
Nx	2	2	3	3	8	8	13	13
Mean	371.0	-1.7	301.3	-98.7	382.9	-0.6	362.2	-23.4
SD	46.67	8.96	219.23	225.39	43.69	29.03	102.61	103.95
Median	371.0	-1.7	410.0	12.0	385.5	7.7	394.0	4.7
Q1, Q3	338.0, 404.0	-8.0, 4.7	49.0, 445.0	-358.0, 50.0	347.0, 412.0	-19.7, 21.3	338.0, 412.0	-8.0, 16.7
Min, Max	338, 404	-8, 5	49, 445	-358, 50	322, 452	-50, 26	49, 452	-358, 50

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Baseline								
Nx	4		7		10		21	
Mean	424.01		408.42		414.50		414.29	
SD	17.419		18.988		20.463		19.315	
Median	424.27		408.33		417.38		417.77	
Q1, Q3	410.60, 437.42		397.17, 426.50		402.87, 431.87		403.43, 427.90	
Min, Max	403.4, 444.1		373.3, 427.2		375.6, 439.4		373.3, 444.1	
Cycle 1 Day 1, 1 Hour Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	419.89	-4.12	405.46	-2.96	414.28	-0.22	412.41	-1.88
SD	20.250	14.389	25.982	10.519	37.184	19.480	30.266	15.420
Median	423.20	-1.53	410.83	0.87	420.68	2.93	413.00	1.80
Q1, Q3	403.90, 435.88	-14.33, 6.10	404.83, 422.47	-6.50, 3.57	399.73, 441.20	-0.13, 9.07	403.50, 433.60	-5.10, 4.90
Min, Max	394.2, 439.0	-23.6, 10.2	349.2, 427.4	-24.1, 7.7	325.9, 453.8	-49.7, 25.9	325.9, 453.8	-49.7, 25.9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 2 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	423.25	-0.76	409.67	1.25	421.38	6.88	417.83	3.55
SD	23.918	15.142	19.715	4.858	18.404	17.448	19.756	13.769
Median	414.53	2.58	410.60	-0.63	422.50	1.48	418.00	2.23
Q1, Q3	407.38, 439.12	-9.73, 8.22	406.03, 422.90	-2.97, 5.60	404.00, 438.07	-1.30, 13.30	406.03, 432.10	-1.47, 5.60
Min, Max	406.0, 457.9	-22.0, 13.8	370.3, 432.1	-4.3, 8.9	396.6, 445.2	-9.9, 51.4	370.3, 457.9	-22.0, 51.4
Cycle 1 Day 1, 3 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	406.63	-17.38	408.76	0.33	413.31	-1.19	410.52	-3.77
SD	26.468	25.952	21.210	7.444	35.791	18.695	28.714	17.922
Median	406.55	-5.98	410.73	2.00	423.23	1.57	411.07	-1.40
Q1, Q3	388.32, 424.93	-31.43, -3.33	405.97, 421.13	-6.43, 8.80	399.57, 434.53	-1.97, 6.63	401.67, 430.37	-5.37, 3.73
Min, Max	374.6, 438.8	-56.2, -1.4	364.4, 429.3	-8.9, 9.8	326.4, 450.9	-49.2, 23.8	326.4, 450.9	-56.2, 23.8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 4 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	401.89	-22.12	405.89	-2.54	415.79	1.29	409.84	-4.44
SD	15.923	11.271	24.365	8.534	28.294	11.875	24.743	13.585
Median	398.60	-18.57	415.67	-3.07	417.48	-1.18	408.90	-2.97
Q1, Q3	389.87, 413.92	-29.63, - 14.60	400.70, 422.33	-6.20, 3.53	399.90, 436.40	-2.97, 4.53	399.90, 424.10	-13.03, 3.53
Min, Max	387.3, 423.1	-38.3, -13.0	354.7, 424.1	-18.6, 7.3	359.8, 457.1	-15.8, 30.0	354.7, 457.1	-38.3, 30.0
Cycle 1 Day 1, 6 Hours Post-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	397.30	-26.71	404.17	-4.26	413.50	-1.00	407.30	-6.98
SD	21.885	22.844	20.194	9.272	35.848	19.146	28.551	19.166
Median	397.33	-26.42	410.93	-9.27	420.73	1.25	410.93	-2.00
Q1, Q3	378.50, 416.10	-42.52, - 10.90	397.07, 417.37	-9.93, 2.83	401.10, 435.20	-2.00, 6.67	397.07, 422.33	-9.93, 2.83
Min, Max	376.1, 418.5	-54.7, 0.7	363.4, 422.3	-11.3, 13.8	325.7, 452.6	-49.9, 25.5	325.7, 452.6	-54.7, 25.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 1, 8 Hours Post-Dose								
Nx	4	4	6	6	10	10	20	20
Mean	401.74	-22.27	403.52	-3.06	414.99	0.49	408.90	-5.13
SD	14.638	6.517	29.221	14.780	17.705	8.582	21.129	13.375
Median	400.20	-23.20	412.67	-0.37	415.90	-3.15	411.12	-3.62
Q1, Q3	389.27, 414.22	-27.53, - 17.00	407.67, 416.40	-10.77, 7.13	399.37, 430.30	-4.63, 7.90	398.80, 425.45	-12.52, 5.72
Min, Max	389.2, 417.4	-28.4, -14.3	345.3, 426.4	-28.0, 14.0	390.3, 439.8	-10.5, 14.7	345.3, 439.8	-28.4, 14.7
Cycle 1 Day 1, 12 Hours Post-Dose								
Nx	4	4	5	5	10	10	19	19
Mean	411.58	-12.43	399.81	-8.65	418.49	3.99	412.12	-2.79
SD	16.028	9.526	34.065	13.467	19.526	27.086	23.580	21.863
Median	408.45	-9.05	408.67	-5.80	408.07	2.38	408.67	-5.30
Q1, Q3	400.22, 422.93	-18.50, -6.37	401.80, 421.37	-6.53, -0.63	406.17, 435.70	-13.20, 7.80	401.80, 433.40	-13.20, 2.53
Min, Max	396.0, 433.4	-26.3, -5.3	341.4, 425.9	-31.9, 1.7	394.5, 449.0	-24.0, 73.4	341.4, 449.0	-31.9, 73.4

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 2, Pre-Dose								
Nx	4	4	7	7	10	10	21	21
Mean	411.80	-12.21	402.59	-5.83	406.64	-7.86	406.27	-8.01
SD	24.543	12.414	22.686	5.490	31.598	15.021	26.551	11.785
Median	403.98	-13.12	401.63	-6.23	407.98	-5.98	401.63	-6.70
Q1, Q3	394.62, 428.98	-22.23, -2.18	396.33, 420.93	-10.67, -0.13	393.43, 438.20	-14.40, 6.13	396.33, 420.93	-14.07, -0.13
Min, Max	392.7, 446.6	-25.1, 2.5	359.2, 428.1	-14.1, 1.6	348.8, 445.5	-36.1, 11.6	348.8, 446.6	-36.1, 11.6
Cycle 1 Day 6, Pre-Dose								
Nx	3	3	6	6	8	8	17	17
Mean	422.03	-4.06	402.73	-5.71	402.28	-12.98	405.92	-8.84
SD	22.335	19.567	18.295	8.830	38.596	38.338	29.628	27.052
Median	414.33	3.13	406.03	-4.37	401.37	-6.23	404.57	-5.87
Q1, Q3	404.57, 447.20	-26.20, 10.90	403.43, 415.00	-11.50, -1.03	383.40, 429.33	-13.58, 2.77	401.10, 418.47	-11.50, 3.13
Min, Max	404.6, 447.2	-26.2, 10.9	367.4, 418.5	-19.2, 6.3	331.2, 458.8	-100.6, 30.9	331.2, 458.8	-100.6, 30.9

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6,								
1 Hour Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	433.20	7.11	408.92	0.48	407.51	-9.06	412.26	-3.19
SD	18.403	9.925	18.679	8.919	35.226	23.623	28.630	18.421
Median	426.87	9.87	409.78	1.13	399.30	-8.37	412.63	-4.27
Q1, Q3	418.80, 453.93	-3.90, 15.37	404.20, 421.77	-4.73, 7.03	389.73, 427.23	-19.50, -4.63	397.70, 427.23	-13.33, 7.03
Min, Max	418.8, 453.9	-3.9, 15.4	376.8, 431.1	-13.3, 11.6	348.3, 470.6	-43.4, 42.7	348.3, 470.6	-43.4, 42.7
Cycle 1 Day 6,								
2 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	422.84	-3.24	406.54	-1.90	410.55	-6.02	411.26	-4.19
SD	23.614	9.777	16.378	8.614	40.742	24.930	30.943	18.147
Median	416.67	-0.50	407.65	-0.65	418.13	-7.53	415.82	-5.32
Q1, Q3	402.93, 448.93	-14.10, 4.87	395.73, 416.30	-11.27, 2.80	395.33, 428.77	-10.60, -1.10	395.73, 428.40	-11.27, 1.90
Min, Max	402.9, 448.9	-14.1, 4.9	383.5, 428.4	-11.8, 10.2	325.8, 475.1	-49.8, 47.2	325.8, 475.1	-49.8, 47.2

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

/projects/noxop254919/stats/primary/prog/tables/t_eg.sas/04JUL2023/01:33

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 6, 3 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	413.38	-12.71	403.91	-4.53	414.40	-2.17	410.73	-4.72
SD	17.734	12.547	22.100	8.355	28.568	16.180	24.280	13.303
Median	404.47	-10.27	407.10	-4.93	414.73	-8.23	409.05	-7.60
Q1, Q3	401.87, 433.80	-26.30, -1.57	391.13, 416.17	-11.00, 3.40	399.43, 429.07	-10.30, -0.13	399.43, 429.07	-11.00, -0.13
Min, Max	401.9, 433.8	-26.3, -1.6	369.3, 432.6	-15.9, 6.1	368.6, 466.1	-14.2, 38.2	368.6, 466.1	-26.3, 38.2
Cycle 1 Day 6, 4 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	416.20	-9.89	406.74	-1.69	409.86	-6.71	409.88	-5.57
SD	22.409	14.745	22.811	6.129	25.638	7.870	23.064	8.664
Median	403.87	-2.00	411.12	-0.73	414.03	-4.50	412.15	-2.67
Q1, Q3	402.67, 442.07	-26.90, -0.77	402.47, 420.40	-8.10, 3.67	398.37, 429.50	-13.07, -2.37	402.47, 429.50	-9.57, 0.90
Min, Max	402.7, 442.1	-26.9, -0.8	365.2, 430.2	-9.6, 5.3	359.1, 436.4	-19.6, 2.6	359.1, 442.1	-26.9, 5.3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 6, 6 Hours Post-Dose								
Nx	3	3	6	6	9	9	18	18
Mean	420.27	-5.82	405.69	-2.74	408.69	-7.88	409.62	-5.83
SD	19.637	6.558	26.371	12.409	20.291	8.669	21.669	9.555
Median	417.43	-2.90	416.57	-4.20	410.47	-6.83	416.57	-5.63
Q1, Q3	402.20, 441.17	-13.33, -1.23	410.33, 418.20	-8.97, 8.73	400.40, 425.27	-10.03, -2.63	402.20, 420.37	-10.03, -1.23
Min, Max	402.2, 441.2	-13.3, -1.2	352.3, 420.2	-21.0, 13.2	365.6, 429.5	-26.7, 2.8	352.3, 441.2	-26.7, 13.2
Cycle 1 Day 14, Pre-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	428.57	2.48	415.23	0.78	414.79	-7.71	418.11	-2.75
SD	15.671	7.978	7.684	12.847	22.132	7.829	17.187	10.034
Median	425.90	1.33	417.23	-3.85	417.58	-8.70	417.63	-4.87
Q1, Q3	414.40, 445.40	-4.87, 10.97	410.55, 419.92	-6.92, 8.47	394.37, 429.97	-13.30, -1.90	409.43, 425.90	-8.87, 1.33
Min, Max	414.4, 445.4	-4.9, 11.0	404.3, 422.2	-8.9, 19.7	385.9, 443.4	-17.7, 4.0	385.9, 445.4	-17.7, 19.7

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 1 Hour Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	415.13	-10.96	416.14	1.68	412.67	-9.83	414.31	-6.55
SD	6.899	16.171	4.874	11.131	22.028	13.861	14.788	13.691
Median	411.17	-19.60	416.78	-1.25	404.47	-6.68	411.17	-5.83
Q1, Q3	411.13, 423.10	-20.97, 7.70	412.13, 420.15	-6.68, 10.05	400.57, 433.33	-20.70, 0.17	406.40, 420.67	-19.60, 3.33
Min, Max	411.1, 423.1	-21.0, 7.7	410.3, 420.7	-7.5, 16.8	387.6, 445.6	-31.3, 6.2	387.6, 445.6	-31.3, 16.8
Cycle 1 Day 14, 2 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	418.89	-7.20	416.96	2.50	418.87	-3.63	418.28	-2.57
SD	15.836	16.050	10.493	15.478	17.823	5.372	14.231	11.373
Median	412.23	-7.10	417.30	-0.13	420.88	-2.40	413.90	-2.77
Q1, Q3	407.47, 436.97	-23.30, 8.80	409.07, 424.85	-8.02, 13.02	404.83, 432.20	-4.83, 0.33	407.47, 429.00	-7.10, 1.17
Min, Max	407.5, 437.0	-23.3, 8.8	404.2, 429.0	-13.3, 23.5	393.9, 440.5	-13.7, 1.2	393.9, 440.5	-23.3, 23.5

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg		1200 mg		1600 mg		N=21	
	N=4		N=7		N=10			
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 1 Day 14, 3 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	416.91	-9.18	414.22	-0.24	419.77	-2.73	417.40	-3.45
SD	19.613	10.259	10.036	10.665	20.666	10.754	16.537	10.298
Median	409.90	-5.00	413.23	-1.55	423.05	-2.63	415.50	-3.77
Q1, Q3	401.77, 439.07	-20.87, -1.67	407.08, 421.35	-7.73, 7.25	407.77, 431.67	-8.93, 6.80	407.77, 428.10	-8.93, 0.70
Min, Max	401.8, 439.1	-20.9, -1.7	403.2, 427.2	-11.7, 13.8	386.9, 446.2	-19.3, 10.3	386.9, 446.2	-20.9, 13.8
Cycle 1 Day 14, 4 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	421.19	-4.90	418.35	3.89	417.36	-5.14	418.55	-2.31
SD	30.480	19.575	13.467	11.554	20.167	9.961	19.290	12.534
Median	404.57	-0.80	414.65	5.30	419.53	-6.52	413.57	-0.80
Q1, Q3	402.63, 456.37	-26.20, 12.30	409.50, 427.20	-5.37, 13.15	407.07, 426.50	-9.73, 5.90	406.57, 426.50	-9.73, 6.03
Min, Max	402.6, 456.4	-26.2, 12.3	406.6, 437.5	-10.3, 15.3	386.1, 445.4	-20.0, 6.0	386.1, 456.4	-26.2, 15.3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 1 Day 14, 6 Hours Post-Dose								
Nx	3	3	4	4	6	6	13	13
Mean	417.86	-8.23	415.05	0.59	419.94	-2.56	417.95	-2.90
SD	10.580	14.254	5.718	10.637	19.598	4.475	13.843	9.040
Median	412.07	-14.00	415.10	1.70	424.17	-2.75	415.30	-3.73
Q1, Q3	411.43, 430.07	-18.70, 8.00	411.45, 418.65	-8.18, 9.37	405.90, 433.73	-6.53, 1.87	411.43, 429.43	-8.20, 3.00
Min, Max	411.4, 430.1	-18.7, 8.0	408.0, 422.0	-11.9, 10.8	389.3, 442.4	-8.2, 3.0	389.3, 442.4	-18.7, 10.8
Cycle 2 Day 1, Pre-Dose								
Nx	2	2	4	4	6	6	12	12
Mean	429.97	-7.45	413.27	-1.19	418.62	5.74	418.73	1.23
SD	23.005	13.600	9.222	16.350	28.769	14.849	21.939	14.727
Median	429.97	-7.45	416.47	-7.60	411.32	5.07	414.12	-2.73
Q1, Q3	413.70, 446.23	-17.07, 2.17	407.22, 419.32	-10.37, 7.98	394.63, 447.87	-8.23, 10.47	404.60, 433.23	-8.62, 9.48
Min, Max	413.7, 446.2	-17.1, 2.2	399.9, 420.2	-12.6, 23.1	387.6, 459.0	-9.0, 31.1	387.6, 459.0	-17.1, 31.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 2 Day 1, 1 Hour Post-Dose								
Nx	2	2	4	4	5	5	11	11
Mean	457.52	20.10	409.87	-4.59	413.92	4.05	420.37	3.82
SD	15.014	5.610	5.363	15.851	17.958	4.744	22.385	12.995
Median	457.52	20.10	409.23	-6.53	412.43	3.13	413.10	3.13
Q1, Q3	446.90, 468.13	16.13, 24.07	405.32, 414.42	-16.33, 7.15	403.87, 416.00	0.23, 8.33	405.27, 442.50	-1.63, 15.93
Min, Max	446.9, 468.1	16.1, 24.1	405.3, 415.7	-21.2, 15.9	394.8, 442.5	-1.0, 9.6	394.8, 468.1	-21.2, 24.1
Cycle 3 Day 1, Pre-Dose								
Nx	0	0	4	4	4	4	8	8
Mean	NC	NC	417.11	2.65	425.66	7.97	421.38	5.31
SD	NC	NC	7.290	9.795	21.478	4.091	15.536	7.508
Median	NC	NC	415.95	1.52	429.03	8.25	418.53	4.68
Q1, Q3	NC, NC	NC, NC	411.42, 422.80	-4.03, 9.33	408.42, 442.90	4.68, 11.25	411.42, 433.30	1.52, 11.25
Min, Max	NC, NC	NC, NC	410.1, 426.4	-8.0, 15.6	398.9, 445.6	3.1, 12.3	398.9, 445.6	-8.0, 15.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 3 Day 1, 1 Hour Post-Dose								
Nx	1	1	4	4	4	4	9	9
Mean	440.53	-3.53	420.30	5.84	425.60	7.91	424.90	5.72
SD	NC	NC	13.876	11.737	24.266	10.992	18.286	10.491
Median	440.53	-3.53	414.87	10.00	426.70	9.10	416.20	6.53
Q1, Q3	440.53, 440.53	-3.53, -3.53	412.08, 428.52	-2.22, 13.90	404.73, 446.47	-0.15, 15.97	410.63, 440.83	-3.53, 13.47
Min, Max	440.5, 440.5	-3.5, -3.5	410.6, 440.8	-11.0, 14.3	401.4, 447.6	-6.3, 19.7	401.4, 447.6	-11.0, 19.7
Cycle 5 Day 1, Pre-Dose								
Nx	0	0	3	3	4	4	7	7
Mean	NC	NC	419.73	-0.49	412.08	-7.57	415.36	-4.53
SD	NC	NC	17.900	21.562	20.366	13.269	18.192	16.041
Median	NC	NC	419.80	11.10	412.30	-9.65	416.70	-2.97
Q1, Q3	NC, NC	NC, NC	401.80, 437.60	-25.37, 12.80	397.60, 426.55	-18.17, 3.03	401.80, 436.40	-20.00, 11.10
Min, Max	NC, NC	NC, NC	401.8, 437.6	-25.4, 12.8	387.3, 436.4	-20.0, 9.0	387.3, 437.6	-25.4, 12.8

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 7 Day 1, Pre-Dose								
Nx	0	0	2	2	4	4	6	6
Mean	NC	NC	430.70	3.87	409.48	-10.17	416.55	-5.49
SD	NC	NC	4.808	5.280	12.122	16.981	14.592	15.202
Median	NC	NC	430.70	3.87	411.00	-7.82	418.75	-2.93
Q1, Q3	NC, NC	NC, NC	427.30, 434.10	0.13, 7.60	400.20, 418.75	-21.30, 0.97	406.40, 427.30	-9.63, 7.60
Min, Max	NC, NC	NC, NC	427.3, 434.1	0.1, 7.6	394.0, 421.9	-33.0, 7.9	394.0, 434.1	-33.0, 7.9
Cycle 9 Day 1, Pre-Dose								
Nx	0	0	3	3	3	3	6	6
Mean	NC	NC	422.30	5.36	424.17	-0.81	423.23	2.27
SD	NC	NC	10.237	6.914	11.657	16.863	9.865	12.011
Median	NC	NC	427.60	1.63	419.10	8.23	423.35	4.93
Q1, Q3	NC, NC	NC, NC	410.50, 428.80	1.10, 13.33	415.90, 437.50	-20.27, 9.60	415.90, 428.80	1.10, 9.60
Min, Max	NC, NC	NC, NC	410.5, 428.8	1.1, 13.3	415.9, 437.5	-20.3, 9.6	410.5, 437.5	-20.3, 13.3

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4		1200 mg N=7		1600 mg N=10		N=21	
	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline	Value	Change from baseline
Cycle 11 Day 1, Pre-Dose								
Nx	0	0	3	3	2	2	5	5
Mean	NC	NC	418.20	1.26	423.30	5.52	420.24	2.96
SD	NC	NC	10.278	7.056	36.911	22.604	20.031	12.573
Median	NC	NC	423.00	-1.30	423.30	5.52	423.00	-1.30
Q1, Q3	NC, NC	NC, NC	406.40, 425.20	-4.17, 9.23	397.20, 449.40	-10.47, 21.50	406.40, 425.20	-4.17, 9.23
Min, Max	NC, NC	NC, NC	406.4, 425.2	-4.2, 9.2	397.2, 449.4	-10.5, 21.5	397.2, 449.4	-10.5, 21.5
Cycle 13 Day 1, Pre-Dose								
Nx	0	0	1	1	2	2	3	3
Mean	NC	NC	397.20	0.03	421.75	3.97	413.57	2.66
SD	NC	NC	NC	NC	18.738	4.431	19.403	3.870
Median	NC	NC	397.20	0.03	421.75	3.97	408.50	0.83
Q1, Q3	NC, NC	NC, NC	397.20, 397.20	0.03, 0.03	408.50, 435.00	0.83, 7.10	397.20, 435.00	0.03, 7.10
Min, Max	NC, NC	NC, NC	397.2, 397.2	0.0, 0.0	408.5, 435.0	0.8, 7.1	397.2, 435.0	0.0, 7.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 15 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	412.60	15.43	408.50	0.83	410.55	8.13
SD	NC	NC	NC	NC	NC	NC	2.899	10.324
Median	NC	NC	412.60	15.43	408.50	0.83	410.55	8.13
Q1, Q3	NC, NC	NC, NC	412.60, 412.60	15.43, 15.43	408.50, 408.50	0.83, 0.83	408.50, 412.60	0.83, 15.43
Min, Max	NC, NC	NC, NC	412.6, 412.6	15.4, 15.4	408.5, 408.5	0.8, 0.8	408.5, 412.6	0.8, 15.4
Cycle 17 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	414.30	17.13	406.30	-1.37	410.30	7.88
SD	NC	NC	NC	NC	NC	NC	5.657	13.081
Median	NC	NC	414.30	17.13	406.30	-1.37	410.30	7.88
Q1, Q3	NC, NC	NC, NC	414.30, 414.30	17.13, 17.13	406.30, 406.30	-1.37, -1.37	406.30, 414.30	-1.37, 17.13
Min, Max	NC, NC	NC, NC	414.3, 414.3	17.1, 17.1	406.3, 406.3	-1.4, -1.4	406.3, 414.3	-1.4, 17.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 19 Day 1, Pre-Dose								
Nx	0	0	1	1	1	1	2	2
Mean	NC	NC	404.20	7.03	419.60	11.93	411.90	9.48
SD	NC	NC	NC	NC	NC	NC	10.889	3.465
Median	NC	NC	404.20	7.03	419.60	11.93	411.90	9.48
Q1, Q3	NC, NC	NC, NC	404.20, 404.20	7.03, 7.03	419.60, 419.60	11.93, 11.93	404.20, 419.60	7.03, 11.93
Min, Max	NC, NC	NC, NC	404.2, 404.2	7.0, 7.0	419.6, 419.6	11.9, 11.9	404.2, 419.6	7.0, 11.9
Cycle 21 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	399.30	2.13	NC	NC	399.30	2.13
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	399.30	2.13	NC	NC	399.30	2.13
Q1, Q3	NC, NC	NC, NC	399.30, 399.30	2.13, 2.13	NC, NC	NC, NC	399.30, 399.30	2.13, 2.13
Min, Max	NC, NC	NC, NC	399.3, 399.3	2.1, 2.1	NC, NC	NC, NC	399.3, 399.3	2.1, 2.1

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.1
Summary of 12-lead Electrocardiogram Parameters by Treatment Group and Timepoint
(Safety Set)

Parameter: QTc Interval, Aggregate (msec)

Visit, Timepoint	Dose Escalation						Total	
	800 mg N=4	Change from baseline	1200 mg N=7	Change from baseline	1600 mg N=10	Change from baseline	N=21	Change from baseline
Cycle 25 Day 1, Pre-Dose								
Nx	0	0	1	1	0	0	1	1
Mean	NC	NC	402.40	5.23	NC	NC	402.40	5.23
SD	NC	NC	NC	NC	NC	NC	NC	NC
Median	NC	NC	402.40	5.23	NC	NC	402.40	5.23
Q1, Q3	NC, NC	NC, NC	402.40, 402.40	5.23, 5.23	NC, NC	NC, NC	402.40, 402.40	5.23, 5.23
Min, Max	NC, NC	NC, NC	402.4, 402.4	5.2, 5.2	NC, NC	NC, NC	402.4, 402.4	5.2, 5.2
End of Treatment, Pre-Dose								
Nx	2	2	3	3	8	8	13	13
Mean	402.75	-14.35	297.67	-112.78	413.63	-3.57	385.19	-30.43
SD	21.142	40.470	215.747	213.831	24.611	20.823	103.218	101.141
Median	402.75	-14.35	414.50	-12.67	409.70	4.70	410.80	1.47
Q1, Q3	387.80, 417.70	-42.97, 14.27	48.70, 429.80	-358.30, 32.63	402.85, 429.40	-21.12, 11.62	400.60, 419.60	-23.73, 11.93
Min, Max	387.8, 417.7	-43.0, 14.3	48.7, 429.8	-358.3, 32.6	372.1, 453.0	-38.8, 19.8	48.7, 453.0	-358.3, 32.6

N = number of patients in the analysis set; Nx = number of patients with non-missing values.

SD = standard deviation; Min = minimum value; Max = maximum value; Q1 = Quartile 1; Q3 = Quartile 3. NC = Not Calculated.

For those patients whose ECG is done in triplicate, the average of the triplicate measurements was used.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 800 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 1 Day 2				
Normal	0	0	0	0
Abnormal, NCS	1 (25.0)	3 (75.0)	0	4 (100)
Abnormal, CS	0	0	0	0
Total	1 (25.0)	3 (75.0)	0	4 (100)
Cycle 1 Day 6				
Normal	1 (33.3)	0	0	1 (33.3)
Abnormal, NCS	0	2 (66.7)	0	2 (66.7)
Abnormal, CS	0	0	0	0
Total	1 (33.3)	2 (66.7)	0	3 (100)
Cycle 1 Day 14				
Normal	1 (33.3)	0	0	1 (33.3)
Abnormal, NCS	0	2 (66.7)	0	2 (66.7)
Abnormal, CS	0	0	0	0
Total	1 (33.3)	2 (66.7)	0	3 (100)

n = number of patients in the specified category; Percentage (%) = n/total* 100.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 800 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 2 Day 1				
Normal	1 (50.0)	0	0	1 (50.0)
Abnormal, NCS	0	1 (50.0)	0	1 (50.0)
Abnormal, CS	0	0	0	0
Total	1 (50.0)	1 (50.0)	0	2 (100)
Cycle 3 Day 1				
Normal	1 (100)	0	0	1 (100)
Abnormal, NCS	0	0	0	0
Abnormal, CS	0	0	0	0
Total	1 (100)	0	0	1 (100)
End of Treatment				
Normal	0	0	0	0
Abnormal, NCS	0	2 (100)	0	2 (100)
Abnormal, CS	0	0	0	0
Total	0	2 (100)	0	2 (100)

n = number of patients in the specified category; Percentage (%) = n/total* 100.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

/projects/noxop254919/stats/primary/prog/tables/t_eg_shift.sas/04JUL2023/01:33

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1200 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 1 Day 2				
Normal	2 (28.6)	1 (14.3)	0	3 (42.9)
Abnormal, NCS	0	4 (57.1)	0	4 (57.1)
Abnormal, CS	0	0	0	0
Total	2 (28.6)	5 (71.4)	0	7 (100)
Cycle 1 Day 6				
Normal	1 (16.7)	1 (16.7)	0	2 (33.3)
Abnormal, NCS	0	4 (66.7)	0	4 (66.7)
Abnormal, CS	0	0	0	0
Total	1 (16.7)	5 (83.3)	0	6 (100)
Cycle 1 Day 14				
Normal	0	1 (25.0)	0	1 (25.0)
Abnormal, NCS	1 (25.0)	2 (50.0)	0	3 (75.0)
Abnormal, CS	0	0	0	0
Total	1 (25.0)	3 (75.0)	0	4 (100)

n = number of patients in the specified category; Percentage (%) = n/total* 100.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1200 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 2 Day 1				
Normal	0	2 (50.0)	0	2 (50.0)
Abnormal, NCS	1 (25.0)	1 (25.0)	0	2 (50.0)
Abnormal, CS	0	0	0	0
Total	1 (25.0)	3 (75.0)	0	4 (100)
Cycle 3 Day 1				
Normal	0	2 (50.0)	0	2 (50.0)
Abnormal, NCS	1 (25.0)	1 (25.0)	0	2 (50.0)
Abnormal, CS	0	0	0	0
Total	1 (25.0)	3 (75.0)	0	4 (100)
Cycle 5 Day 1				
Normal	0	0	0	0
Abnormal, NCS	0	3 (100)	0	3 (100)
Abnormal, CS	0	0	0	0
Total	0	3 (100)	0	3 (100)

n = number of patients in the specified category; Percentage (%) = $n/\text{total} \times 100$.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1200 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 7 Day 1				
Normal	0	1 (50.0)	0	1 (50.0)
Abnormal, NCS	0	1 (50.0)	0	1 (50.0)
Abnormal, CS	0	0	0	0
Total	0	2 (100)	0	2 (100)
Cycle 9 Day 1				
Normal	0	1 (33.3)	0	1 (33.3)
Abnormal, NCS	1 (33.3)	1 (33.3)	0	2 (66.7)
Abnormal, CS	0	0	0	0
Total	1 (33.3)	2 (66.7)	0	3 (100)
Cycle 11 Day 1				
Normal	1 (33.3)	0	0	1 (33.3)
Abnormal, NCS	0	2 (66.7)	0	2 (66.7)
Abnormal, CS	0	0	0	0
Total	1 (33.3)	2 (66.7)	0	3 (100)

n = number of patients in the specified category; Percentage (%) = n/total* 100.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1200 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 13 Day 1				
Normal	1 (100)	0	0	1 (100)
Abnormal, NCS	0	0	0	0
Abnormal, CS	0	0	0	0
Total	1 (100)	0	0	1 (100)
Cycle 15 Day 1				
Normal	1 (100)	0	0	1 (100)
Abnormal, NCS	0	0	0	0
Abnormal, CS	0	0	0	0
Total	1 (100)	0	0	1 (100)
Cycle 17 Day 1				
Normal	1 (100)	0	0	1 (100)
Abnormal, NCS	0	0	0	0
Abnormal, CS	0	0	0	0
Total	1 (100)	0	0	1 (100)

n = number of patients in the specified category; Percentage (%) = n/total* 100.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1200 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 19 Day 1				
Normal	1 (100)	0	0	1 (100)
Abnormal, NCS	0	0	0	0
Abnormal, CS	0	0	0	0
Total	1 (100)	0	0	1 (100)
Cycle 21 Day 1				
Normal	1 (100)	0	0	1 (100)
Abnormal, NCS	0	0	0	0
Abnormal, CS	0	0	0	0
Total	1 (100)	0	0	1 (100)
Cycle 25 Day 1				
Normal	0	0	0	0
Abnormal, NCS	1 (100)	0	0	1 (100)
Abnormal, CS	0	0	0	0
Total	1 (100)	0	0	1 (100)

n = number of patients in the specified category; Percentage (%) = $n/\text{total} \times 100$.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1200 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
End of Treatment				
Normal	0	1 (33.3)	0	1 (33.3)
Abnormal, NCS	1 (33.3)	1 (33.3)	0	2 (66.7)
Abnormal, CS	0	0	0	0
Total	1 (33.3)	2 (66.7)	0	3 (100)

n = number of patients in the specified category; Percentage (%) = $n/\text{total} \times 100$.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1600 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 1 Day 2				
Normal	4 (40.0)	1 (10.0)	0	5 (50.0)
Abnormal, NCS	0	5 (50.0)	0	5 (50.0)
Abnormal, CS	0	0	0	0
Total	4 (40.0)	6 (60.0)	0	10 (100)
Cycle 1 Day 6				
Normal	3 (33.3)	1 (11.1)	0	4 (44.4)
Abnormal, NCS	0	5 (55.6)	0	5 (55.6)
Abnormal, CS	0	0	0	0
Total	3 (33.3)	6 (66.7)	0	9 (100)
Cycle 1 Day 14				
Normal	3 (50.0)	0	0	3 (50.0)
Abnormal, NCS	0	3 (50.0)	0	3 (50.0)
Abnormal, CS	0	0	0	0
Total	3 (50.0)	3 (50.0)	0	6 (100)

n = number of patients in the specified category; Percentage (%) = n/total* 100.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1600 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 2 Day 1				
Normal	3 (50.0)	0	0	3 (50.0)
Abnormal, NCS	0	3 (50.0)	0	3 (50.0)
Abnormal, CS	0	0	0	0
Total	3 (50.0)	3 (50.0)	0	6 (100)
Cycle 3 Day 1				
Normal	1 (25.0)	0	0	1 (25.0)
Abnormal, NCS	1 (25.0)	2 (50.0)	0	3 (75.0)
Abnormal, CS	0	0	0	0
Total	2 (50.0)	2 (50.0)	0	4 (100)
Cycle 5 Day 1				
Normal	1 (25.0)	0	0	1 (25.0)
Abnormal, NCS	0	3 (75.0)	0	3 (75.0)
Abnormal, CS	0	0	0	0
Total	1 (25.0)	3 (75.0)	0	4 (100)

n = number of patients in the specified category; Percentage (%) = n/total* 100.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1600 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 7 Day 1				
Normal	1 (25.0)	0	0	1 (25.0)
Abnormal, NCS	0	3 (75.0)	0	3 (75.0)
Abnormal, CS	0	0	0	0
Total	1 (25.0)	3 (75.0)	0	4 (100)
Cycle 9 Day 1				
Normal	1 (33.3)	0	0	1 (33.3)
Abnormal, NCS	0	1 (33.3)	0	1 (33.3)
Abnormal, CS	0	1 (33.3)	0	1 (33.3)
Total	1 (33.3)	2 (66.7)	0	3 (100)
Cycle 11 Day 1				
Normal	1 (50.0)	0	0	1 (50.0)
Abnormal, NCS	0	1 (50.0)	0	1 (50.0)
Abnormal, CS	0	0	0	0
Total	1 (50.0)	1 (50.0)	0	2 (100)

n = number of patients in the specified category; Percentage (%) = n/total* 100.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1600 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 13 Day 1				
Normal	1 (50.0)	0	0	1 (50.0)
Abnormal, NCS	0	1 (50.0)	0	1 (50.0)
Abnormal, CS	0	0	0	0
Total	1 (50.0)	1 (50.0)	0	2 (100)
Cycle 15 Day 1				
Normal	1 (100)	0	0	1 (100)
Abnormal, NCS	0	0	0	0
Abnormal, CS	0	0	0	0
Total	1 (100)	0	0	1 (100)
Cycle 17 Day 1				
Normal	0	0	0	0
Abnormal, NCS	0	0	0	0
Abnormal, CS	1 (100)	0	0	1 (100)
Total	1 (100)	0	0	1 (100)

n = number of patients in the specified category; Percentage (%) = n/total* 100.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Table 14.3-4.3.2
Shift Summary of 12-lead Electrocardiogram Assessments by Timepoint
(Safety Set)

Treatment Group: Dose Escalation 1600 mg

Visit	Baseline			Total n (%)
	Normal n (%)	Abnormal, NCS n (%)	Abnormal, CS n (%)	
Cycle 19 Day 1				
Normal	1 (100)	0	0	1 (100)
Abnormal, NCS	0	0	0	0
Abnormal, CS	0	0	0	0
Total	1 (100)	0	0	1 (100)
End of Treatment				
Normal	3 (37.5)	0	0	3 (37.5)
Abnormal, NCS	1 (12.5)	3 (37.5)	0	4 (50.0)
Abnormal, CS	0	1 (12.5)	0	1 (12.5)
Total	4 (50.0)	4 (50.0)	0	8 (100)

n = number of patients in the specified category; Percentage (%) = $n/\text{total} \times 100$.

NCS = Not clinically significant; CS = Clinically significant.

Baseline is defined as the last available pre-treatment assessment before the first dose at Day 1 of Cycle 1.

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Appendix 16.3 Case Report Forms

Appendix 16.3.1 CRFs for Deaths, Other Serious Adverse Events, and Withdrawals for Adverse Events

Completed CRFs are provided for the 8 patients who experienced TESAEs and the additional patient who discontinued due to a TEAE:

- [Patient 200105](#): SAE of acute respiratory failure (fatal)
- [Patient 200204](#): SAEs of anemia and non-cardiac chest pain
- [Patient 200207](#): SAEs of encephalopathy and failure to thrive
- [Patient 200211](#): SAE of pleural effusion
- [Patient 200107](#): SAE of diarrhea
- [Patient 200212](#): SAEs of pain in extremity, sinus tachycardia, and respiratory distress
- [Patient 200213](#): SAE of angina pectoris
- [Patient 300201](#): SAEs of confusional state and general physical health deterioration (latter led to study discontinuation)
- [Patient 300202](#): TEAE of abdominal distension that led to study discontinuation