CLINICAL STUDY REPORT ADDENDUM

G1T28-04

PHASE 2 STUDY OF THE SAFETY, EFFICACY, AND PHARMACOKINETICS OF G1T28 IN PATIENTS WITH METASTATIC TRIPLE NEGATIVE BREAST CANCER RECEIVING GEMCITABINE AND CARBOPLATIN CHEMOTHERAPY

Indication studied:	Prevention or mitigation of chemotherapy-induced myelosuppression
Investigational product:	Trilaciclib (G1T28)
Developmental phase of study:	2
ClinicalTrials.gov identifier:	NCT02978716
EudraCT number:	2016-004466-26
Release date of report:	9 December 2020
Company/Sponsor signatory:	Andy Beelen, MD Vice President, Clinical Development G1 Therapeutics, Inc. Email: abeelen@g1therapeutics.com
Coordinating investigator:	Antoinette Tan, MD Levine Cancer Institute Email: Antoinette.Tan@atriumhealth.org

This study was conducted in accordance with the ethical principles of Good Clinical Practice, including archiving of essential documents, and according to the ICH Harmonized Tripartite Guideline.

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3. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

The following abbreviations and specialized terms are used in this study report addendum.

Table 1: Abbreviations and Specialist Terms

Abbreviation or Specialist Term	Explanation
AE	adverse event
ATC	Anatomical Therapeutic Classification
CDK	cyclin-dependent kinase
CI	confidence interval
CSR	clinical study report
CTCAE	Common Terminology Criteria for Adverse Events
DBL	database lock
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic case report form
GC	gemcitabine and carboplatin
HR	hazard ratio
IFNγ	interferon-gamma
IHC	immunohistochemistry
ITT	intent-to-treat
IV	intravenous(ly)
NDA	New Drug Application
ORR	objective response rate
OS	overall survival
PD-L1	programmed death-ligand 1
PFS	progression-free survival
PK	pharmacokinetic(s)
PT	preferred term
SAE	serious adverse event
SAP	Statistical Analysis Plan
TCR	T cell receptor
TEAE	treatment-emergent adverse event
TFLs	tables, listings, and figures
TNBC	triple negative breast cancer

Abbreviation or Specialist Term	Explanation
WHO-DD	World Health Organization Drug Dictionary

4. INTRODUCTION

4.1. Study Design

This was a global, multicenter, randomized, open-label, Phase 2 trial of the safety, efficacy, and pharmacokinetics (PK) of trilaciclib in combination with gemcitabine and carboplatin (GC) therapy for patients with locally recurrent/metastatic triple negative breast cancer (TNBC). Based on its mechanism of action, trilaciclib administered before chemotherapy has the potential to enhance immune activity in patients with TNBC while protecting the bone marrow from the cytotoxic effects of chemotherapy, potentially improving both anti-tumor activity and safety. A total of 102 patients were randomly assigned (1:1:1 fashion) to one of the following 3 groups (Figure 1):

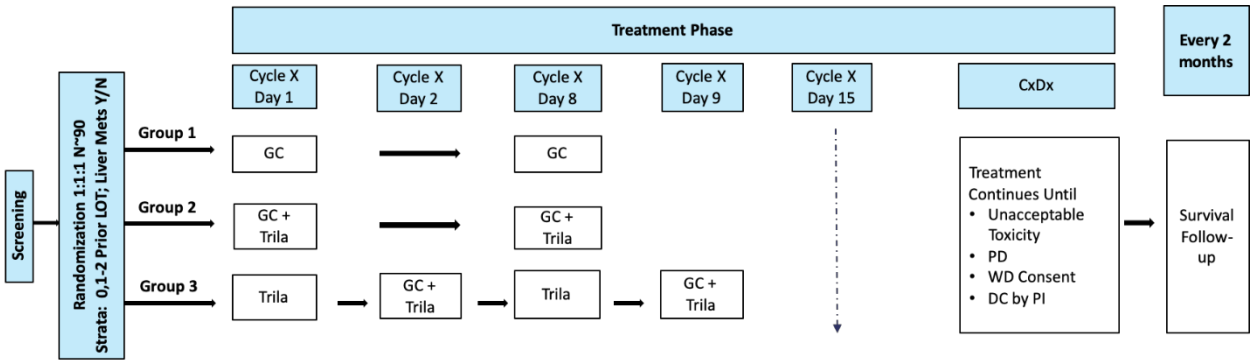
- GC therapy only on Days 1 and 8 of 21-day cycles (n=34) (hereafter referred to as Group 1)
- Trilaciclib administered intravenously (IV) on Days 1 and 8 of 21-day cycles plus GC (Days 1 and 8) (n=33) (hereafter referred to as Group 2)
- Trilaciclib administered IV on Days 1, 2, 8, and 9 of 21-day cycles plus GC therapy (Days 2 and 9) (n=35) (hereafter referred to as Group 3)

Note: Trilaciclib was administered over 30 (±5) minutes prior to GC dosing. The interval between trilaciclib administration and the first dose of chemotherapy (gemcitabine or carboplatin) administration should not have been greater than 4 hours. The interval between doses of trilaciclib on successive days in Group 3 was not to be > 28 hours.

Patients were determined by the investigator to have a diagnosis of locally recurrent/metastatic TNBC at the time of enrollment. All statistical analyses used the stratification variables of liver involvement (Yes or No) and the number of prior lines of anti-cancer therapy (0 versus 1 or 2) in the locally recurrent/metastatic setting at the time of randomization.

The study included 3 phases: Screening Phase, Treatment Phase, and Survival Follow-Up Phase (Figure 1). The Treatment Phase began on the day of the first dose of study drug and was completed at the Post-Treatment Visit. Patients were then followed for long-term survival every 2 months through the end of the study.

Figure 1: Study Schema (All Enrolled Patients)



DC=discontinuation; GC=gemcitabine and carboplatin; LOT=lines of therapy; PD=progressive disease; PI=principal investigator; Trila=trilaciclib; WD=withdrew.

4.2. Rationale for G1T28-04 CSR Addendum

A database lock (database lock 2 [DBL2]; 28 June 2019) occurred to support filing of the trilaciclib New Drug Application (NDA). The G1T28-04 Clinical Study Report (CSR) released in January 2020 reported final myelopreservation efficacy results and interim anti-tumor efficacy and safety results. At the time of DBL2, 2 patients were still receiving study drug and 35 patients were still in survival follow-up for Study G1T28-04. The study has now been completed and the final database lock occurred on 17 July 2020 (with a last patient last visit date of 28 February 2020). The rationale for this CSR addendum is to provide a summary of the complete patient disposition, protocol deviations, subsequent anticancer therapy, and overall survival (OS) based on the End-of-Study analysis, as well as details for adverse events (AEs) recorded between DBL2 and the final database lock.

5. DATA MANAGEMENT AND QUALITY ASSURANCE

The Sponsor conducted this study according to procedures that incorporate the ethical principles of Good Clinical Practice. Training on the protocol and study-specific procedures was provided to the investigator and study site staff during the site initiation visits and throughout the course of the study, as appropriate. Training was also provided to the clinical research associates prior to the first site initiation visit and throughout the course of the study, as appropriate or as staff changed.

Qualified representatives of the Sponsor or Sponsor designees (study monitors) monitored the study according to a pre-determined monitoring plan. The investigator was required to permit the study monitors to periodically review all electronic case report forms (eCRFs) and source documents supporting the participation of each patient in the study. The eCRFs and other documentation supporting the study had to be kept up to date by the investigator and the staff at the study site. These study materials had to be available for review by the study monitor and/or other qualified representatives of the Sponsor at each monitoring visit and were provided in such a way that the patient's confidentiality was maintained in accordance with local institution, state, country, and federal requirements.

Reported protocol deviations were reviewed on an ongoing basis throughout the study. Deviations were monitored at the time of each DBL and classified as key (those that affected the assessment of the safety and efficacy of the study drug leading to exclusion from the per protocol analysis set) or non-key (major or minor) based on the study-specific Protocol Deviation Guidance document (Protocol Deviation Criteria Version 3.0).

An eCRF was completed for each patient screened (defined as a patient who signed the informed consent form). If a patient withdrew from study treatment, the reason for discontinuing each study treatment was to be noted on the eCRF, and if a patient was withdrawn from the treatment because of a treatment-limiting AE, thorough efforts were to be made to clearly document the outcome. The same applies to a patient withdrawing from the study. The investigator was to ensure the accuracy, completeness, legibility, and timeliness of the data reported to the Sponsor in the eCRFs and in all required reports.

Accurate and reliable data collection was ensured by verification and cross-check of the eCRFs against the investigator's records by the study monitor (source document verification) and the maintenance of a drug dispensing log by the investigator. All data was source data verified with the exception of 2 eCRF pages at Site 1127. These 2 eCRF pages were not source data verified due to COVID-19 restrictions at the site prohibiting the monitor from performing an onsite visit. For these 2 pages, the investigator provided their signature attesting to the accuracy of the data. No audits were conducted between DBL2 and this final database lock.

A comprehensive validation check program verified the data, and discrepancy reports were generated accordingly for resolution by the investigator. As patients completed the study (or withdrew) and their eCRFs became available for review, a comparison check was run to identify and resolve any discrepancies in the database.

6. STATISTICAL METHODS

As described in the original study Statistical Analysis Plan (SAP), the End-of-Study analysis was planned to be conducted when at least 70% of the patients had died. Anti-tumor efficacy (specifically OS) and safety are the focus of this End-of-Study analysis. The final DBL occurred on 17 July 2020 (with a last patient last visit date of 28 February 2020) to create the final statistical package. The full SAP was provided with the submission of the G1T28-04 CSR (release date 20 January 2020); details regarding analyses conducted in this addendum are provided below.

6.1. Analysis Sets

6.1.1. Intent-to-Treat Analysis Set

The Intent-to-Treat (ITT) analysis set included all randomized patients. Analyses using the ITT were conducted on the basis of the assigned treatment. The ITT was used for analyses of OS.

6.1.2. Safety Analysis Set

The safety analysis set included all enrolled patients who received at least 1 dose of study drug (gemcitabine, carboplatin, or trilaciclib). Analyses using the safety analysis set were conducted on the basis of the actual treatment received. All safety analyses were assessed using the safety analysis set.

6.2. Patient Disposition

A summary table was generated to provide the following:

- Number of patients screened
- Number and percentage of screening failures
- Reason for screening failure
- Number of patients dosed
- Number of patients randomized
- Number of patients randomized and not dosed

Patient status at treatment and study completion was listed and summarized. The listing includes whether patients discontinued from the treatment and the reasons for the discontinuation, along with the date of first and last dose. The reason and date of discontinuation was also provided for patients who discontinued from the study.

The following summaries were included in the disposition table:

- End of treatment status (discontinued/ongoing for each study drug)
- Reason for study drug discontinuation (for each study drug)
- Number of patients going into Survival follow-up

- Number and percentage of patients who discontinued the study
- Reason for study discontinuation
- Death and reason for death

6.3. Protocol Deviations

Certain protocol deviations were considered key in that they affected the ability to assess the safety and efficacy of study drug to such an extent that the data was excluded from data analysis. Protocol deviations were reviewed in a data review meeting to classify protocol deviations as non-key (major or minor) or key, and to discuss the potential impact on statistical analysis.

Of note, in the tables, listings, and figures (TFLs) associated with this addendum, as well as the initial CSR, deviations are reported as 'key' and 'key deviation leading to exclusion from the per protocol analysis set'. This terminology was updated in the CSR to more accurately reflect the clinical significance of these deviations. 'Key deviations leading to exclusion from the per protocol analysis set' are reported as 'Key Protocol Deviations' in the CSR. In contrast, deviations reported as 'Key' in the TLFs did not result in exclusion of data from the analysis but could still have impacted the assessment of safety and efficacy and are thus reported as 'Major Protocol Deviations' in the CSR.

6.4. Subsequent Anti-Cancer Therapy

All verbatim terms collected of subsequent anti-cancer therapy were coded to Anatomical Therapeutic Classification (ATC) and preferred term (PT) using the World Health Organization Drug Dictionary (WHO-DD) Version Sep 2017.

The subsequent anti-cancer therapy was summarized by presenting the number and percentage of patients by PT and ATC. Patients taking the same medication multiple times were only counted once for that PT or ATC. The summary was ordered by descending order of incidence of ATC class and PT within each ATC class. The data were presented in a patient listing.

For subsequent anti-cancer therapy, if the term contained the word "RADIATION" or 'RADIOTHERAPY', the therapy was classified to radiotherapy; it was otherwise classified as systemic anti-cancer therapy unless the therapy could be grouped to surgery. The number and percentage of randomized patients receiving subsequent anti-cancer therapy was provided by systemic anti-cancer therapy (by drug name and by line), radiotherapy, and surgery (all other therapeutic products). All subsequent anti-cancer therapies were presented in a patient listing.

6.5. Overall Survival

Overall survival was calculated as the time (months) from date of randomization to the date of death due to any cause. Patients who did not die during the study were censored at the date last known to be alive. Patients lacking data beyond the date of randomization had their survival time censored at date of randomization. OS was not censored if a patient received other anti-tumor treatments after the study drugs.

OS was summarized using the Kaplan-Meier method, and the descriptive statistics of the median, 25th and 75th percentiles, and their 95% confidence intervals (CIs) were calculated. In addition,

Kaplan-Meier estimates were provided for the survival rates at 3, 6, 9, and 12 months along with their 95% CIs.

The primary comparison was conducted between Group 3 (trilaciclib on Days 1/2 and 8/9 with GC on Days 2 and 9) and Group 1 (GC therapy alone). The 2 additional comparisons (ie, trilaciclib/GC on Days 1 and 8 versus GC therapy only and the combined trilaciclib + GC therapy versus GC therapy only) were considered supportive of the primary analyses. However, anti-tumor efficacy endpoints were not subjected to formal statistical testing; therefore, reported p-values are nominal. The 2-sided p-value was obtained from the stratified log-rank test to account for the stratification factors. The hazard ratio (HR) between the 2 treatments (Group 3, Group 2, or the combination versus GC only), together with its 95% CIs, was calculated from a Cox regression model in which treatment and the stratification factors were included as fixed effects.

6.5.1. Subgroup Analyses

Overall survival was also examined in the following subgroups:

- Age group (ages <65; ≥65).
- Liver involvement (Yes; No).
- Eastern Cooperative Oncology Group (ECOG) performance status (0; 1).
- Prior lines of therapy (0; 1-2).
- Race (Caucasian; non-Caucasian).
- Region (US; Ex-US).
- Breast cancer gene (BRCA) classification (Positive; Unknown)
- Histological classification (TNBC; Acquired TNBC)

Descriptive statistics by treatment group were presented for each subgroup of patients. A forest plot is presented for the primary comparison between Group 3 and Group 1.

6.6. Exploratory Analyses

6.6.1. Genetic (DNA) and/or Expression (RNA/Protein) Biomarkers in Tumors and Blood

Archival tumor tissue was collected from patients at the time of the TNBC diagnosis and subjected to signature analysis based on published literature (PAM50 and Lehmann TNBC type) in an effort to characterize patient tumors into 1 of the following 3 groups: cyclin-dependent kinase (CDK)4/6 independent, CDK4/6 dependent, and CDK4/6 indeterminate (Lehmann 2016; Prat 2014). To better characterize the patient population to whom trilaciclib offers clinical benefit, ad hoc subgroup analyses were conducted to evaluate CDK4/6 signature categories relative to the objective response rate (ORR), progression-free survival (PFS), and OS endpoints.

6.6.2. Immunologic Markers

To evaluate the impact of trilaciclib administration according to immunologic subgroups, programmed death-ligand 1 (PD-L1) expression was evaluated using immunohistochemistry (IHC) from archival tumor tissue collected at screening and retrospectively characterized as described below:

- PD-L1 expression (scored as negative or positive if < 1% or ≥ 1% of the total tumor area contained PD-L1–labelled immune cells, respectively, using the Ventana SP142 assay; Ventana 2016)

In addition to evaluating PD-L1 status, RNA was isolated from archival tumor tissue collected at screening and retrospectively characterized as described below.

- Three RNA-based immune signatures identified via literature review:
  - An interferon-gamma (IFNγ) signature based on 6 genes (patients were classified as having high or low gene expression; Ayers 2017)
  - An expanded IFNγ signature based on 18 genes (patients were classified as having high or low gene expression; Ayers 2017)
  - An immune signature based on 6 identified immune response subtypes (patients were classified as being IFNγ dominant [Class 2)] or not; Thorsson 2018)

Association of PD-L1 expression and immune signatures with antitumor efficacy (ORR, PFS and OS) was assessed using proportional hazards regression.

To assess the effect of trilaciclib on the composition of lymphocyte subsets and clonal expansion, T-cell receptor (TCR) β CDR3 regions were amplified and sequenced from purified genomic DNA in peripheral blood mononuclear cells isolated from whole blood samples collected on Day 1 of Cycles 1 (baseline), 3, and 5. Differences in Simpson clonality and clonal expansion were compared between patients receiving trilaciclib plus GC therapy and GC therapy alone and also correlated with clinical outcome (ORR and OS).

6.7. Adverse Events

Adverse events and serious adverse events (SAEs) occurring after DBL2 (28 June 2019) were listed by patient.

7. STUDY PATIENTS

7.1. Disposition of Patients

The G1T28-04 CSR released on 20 January 2020 reported final myelopreservation efficacy results and interim anti-tumor efficacy and safety results. At that time (DBL2), 2 patients (1111003 and 1122001) in Group 2 were still on treatment, and 6 patients in Group 1, 15 patients in Group 2, and 14 patients in Group 3 remained ongoing in the study.

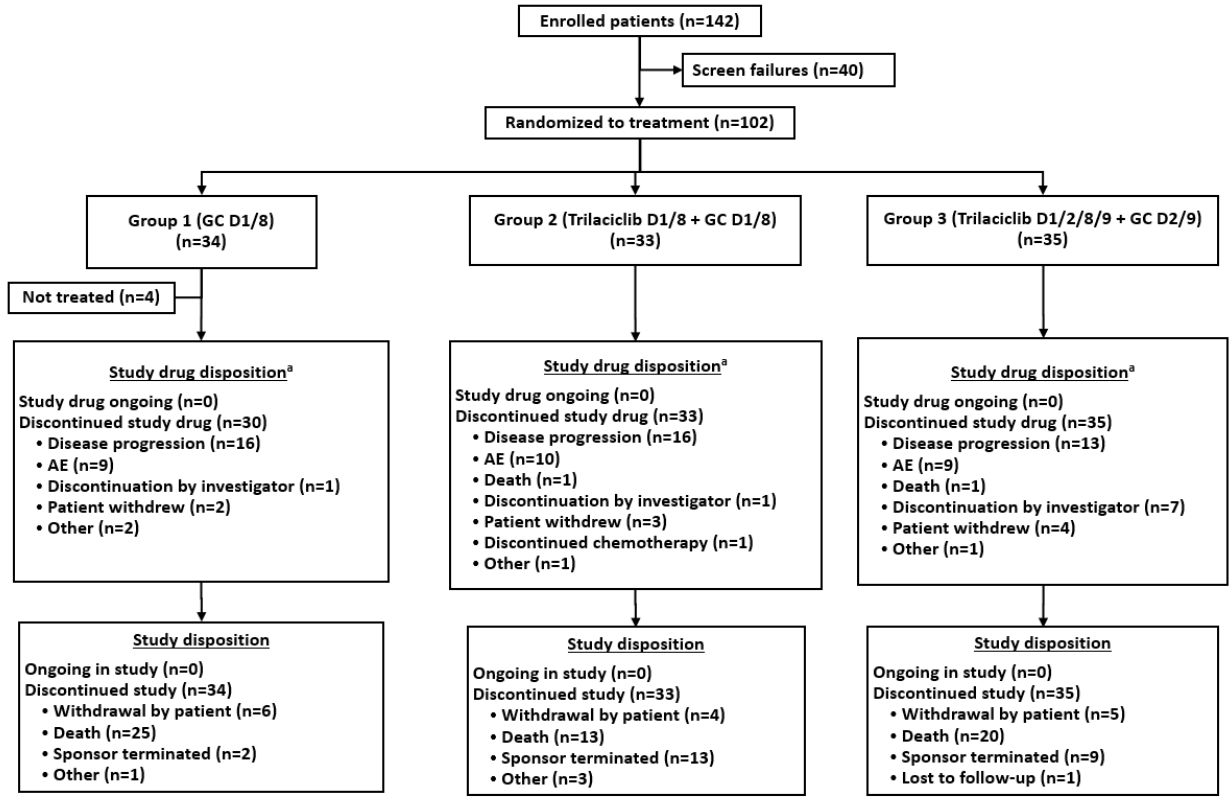
As of the final database lock (17 July 2020; last patient last visit date of 28 February 2020), there were no patients who continued to receive study drug or who remained ongoing in the study. All 98 patients (100%) discontinued study drug, including 30 patients in Group 1, 33 patients in Group 2, and 35 patients in Group 3 (Table 14.1.1.1). The most common reason for discontinuation of study drug was disease progression (53.3%, Group 1; 48.5%, Group 2; and 37.1%, Group 3). All patients had discontinued the study, with the most common reason for discontinuation being death (58 patients [56.9%]), followed by Sponsor terminated study (24 patients [23.5%]). Of the 58 patients who died, the majority (51 [87.9%]) were attributed to disease progression of their underlying TNBC.

Between DBL2 and this final analysis, 2 patients in Group 2 discontinued study drug, including 1 patient who discontinued due to an AE and 1 patient who discontinued due to disease progression (Listing 16.2.1.1.I). Additional details for the patient who discontinued due to an AE are provided in Section 10.2.3. Additional details for the patient who discontinued due to disease progression are provided in the patient narrative (1122001) in Section 13.2.

In addition, a total of 35 patients discontinued from the study between DBL2 and this End-of-Study analysis. These included 11 deaths (4 patients in Group 1, 2 patients in Group 2, and 5 patients in Group 3) and 24 Sponsor terminations (2 patients in Group 1, 13 patients in Group 2, and 9 patients in Group 3) (Listing 16.2.1.2.I). Note that Study G1T28-04 was terminated after (1) all patients had discontinued study drug, (2) the safety follow-up period of 30 days after the last dose of study drug had been completed for all patients, and (3) the necessary data to meet the primary objectives of the study had been collected.

Ten of the 11 deaths occurring between DBL2 and this final analysis were due to disease progression (3 patients in Group 1, 2 patients in Group 2, and 5 patients in Group 3) (Listing 16.2.1.2.I). One patient in Group 1 (GC only) died due to cardiopulmonary failure.

Figure 2: Patient Disposition for Study G1T28-04 (All Enrolled Patients)



AE=adverse event; DBL=database lock; GC=gemcitabine and carboplatin; n=number of patients.

[a] Only treated patients were included. Patients were treated until disease progression, unacceptable toxicity, or discontinuation by patient or investigator decision; therefore, there is no definition of completion for this clinical trial.

Source: Table 14.1.1.1 (from final DBL on 17 July 2020 [with last patient last visit date of 28 February 2020]).

7.2. Protocol Deviations

Protocol deviations were reported overall in the study for 28 patients (82.4%) in Group 1, 31 patients (93.9%) in Group 2, and 34 patients (97.1%) in Group 3 (Table 2).

Table 2: Protocol Deviations (All Randomized Patients)

Protocol Deviations	Number (%) of Patients		
	Group 1 GC (Day 1+8) (N=34)	**Group 2 GC + Trilaciclib (Day 1+8) (N=33)**	**Group 3 GC + Trilaciclib (Day 1/2+8/9) (N=35)**
Number of patients with at least 1 protocol deviation	**28 (82.4)**	**31 (93.9)**	**34 (97.1)**
Visit/procedure required	24 (70.6)	25 (75.8)	27 (77.1)
Laboratory	16 (47.1)	22 (66.7)	19 (54.3)
Visit schedule	15 (44.1)	21 (63.6)	20 (57.1)
Dosing	11 (32.4)	20 (60.6)	6 (17.1)
Concomitant medications	7 (20.6)	7 (21.2)	7 (20.0)
Noncompliance	1 (2.9)	4 (12.1)	7 (20.0)
Enrollment criteria	4 (11.8)	2 (6.1)	2 (5.7)
Informed consent	3 (8.8)	3 (9.1)	0
Regulatory	0	2 (6.1)	2 (5.7)
Other	0	2 (6.1)	0

DBL=database lock; GC=gemcitabine and carboplatin; N=total number of patients in each treatment group.
Note: A patient with multiple entries in the same deviation was counted only once within a particular deviation.
Note: The number (%) of patients with deviations was sorted in decreasing order of frequency (by all treatment groups). If the frequencies tied, an alphabetical order was applied.
Note: Unless otherwise specified, percentages were based on the number of patients in each treatment group.
Source: Table 14.1.2.1 (final DBL on 17 July 2020).

All protocol deviations are listed by patient in Listing 16.2.2.2.

7.2.1. Major Protocol Deviations

Major protocol deviations are summarized in Table 3. Major protocol deviations were those that could have potentially affected the assessment of the safety and efficacy of the study drug but did not require exclusion from the data analysis. Protocol deviations were reviewed in a data review meeting and a Protocol Deviation Criteria document was used to guide the classification of deviations as minor, major, or key (Appendix 16.2.2 G1T28-04 CSR, Protocol Deviation Criteria Version 3.0).

Overall, 13 patients (38.2%) in Group 1, 16 patients (48.5%) in Group 2, and 16 patients (45.7%) in Group 3 had at least 1 major protocol deviation recorded, with the most common categories being dosing (e.g., anything related to dose reductions, delays, and dose skipping; over/underdosing) and visit schedule. Between DBL2 (28 June 2019) and this final database lock, there were 3 new major protocol deviations identified relating to informed consent, laboratory assessment, and non-compliance.

Table 3: Major Protocol Deviations (All Randomized Patients)

Protocol Deviations	Number (%) of Patients		
	Group 1 GC (Day 1+8) (N=34)	**Group 2 GC + Trilaciclib (Day 1+8) (N=33)**	**Group 3 GC + Trilaciclib (Day 1/2+8/9) (N=35)**
Number of patients with at least 1 major deviation	**13 (38.2)**	**16 (48.5)**	**16 (45.7)**
Dosing	5 (14.7)	6 (18.2)	2 (5.7)
Visit schedule	2 (5.9)	6 (18.2)	5 (14.3)
Noncompliance	1 (2.9)	4 (12.1)	6 (17.1)
Concomitant medications	4 (11.8)	3 (9.1)	3 (8.6)
Laboratory	0	1 (3.0)	6 (17.1)
Enrollment criteria	3 (8.8)	1 (3.0)	1 (2.9)
Informed consent	2 (5.9)	3 (9.1)	0
Regulatory	0	2 (6.1)	2 (5.7)
Other	0	1 (3.0)	0
Visit/procedure required	0	0	1 (2.9)

DBL=database lock; GC=gemcitabine and carboplatin; N=total number of patients in each treatment group.
Note: A patient with multiple entries in the same deviation was counted once within a particular deviation.
Note: The number (%) of patients with deviations was sorted in decreasing order of frequency (by all treatment groups). If the frequencies tied, an alphabetical order was applied.
Note: Unless otherwise specified, percentages were based on the number of patients in each treatment group.
Note: Major protocol deviations were those that could have potentially affected the assessment of the safety and efficacy of the study drug but did not require exclusion from data analysis.
Source: Table 14.1.2.1 (final DBL on 17 July 2020).

Key protocol deviations leading to exclusion from the per protocol analysis set were described in the G1T28-04 CSR (Section 10.2.1.2). No new key protocol deviations were identified between DBL2 and this final DBL.

7.3. Subsequent Anti-cancer Therapies

A summary of subsequent systemic anti-cancer therapy is presented in Table 14.1.5.3. A total of 20 patients (58.8%) in Group 1, 20 patients (60.6%) in Group 2, and 23 patients (65.7%) in Group 3 received subsequent anti-cancer therapy. The most common subsequent systemic anti-cancer therapies reported were the continuation of gemcitabine and/or carboplatin after on-study gemcitabine and/or carboplatin was discontinued due to protocol requirements (i.e., hematologic toxicities) and eribulin use.

Subsequent anti-cancer therapies are listed by patient in Listing 16.2.4.7.2.

8. ANTI-TUMOR EFFICACY EVALUATION

8.1. Overall Survival

Results of the OS analysis for the ITT analysis set are summarized in Table 4 and Figure 3. ORR and PFS were considered final at DBL2 and therefore are not presented in this addendum. Anti-tumor efficacy endpoints were not subjected to formal statistical testing; therefore, p-values presented below are nominal.

The percentage of patients who died was higher in Group 1 (73.5%) compared with Group 2 or Group 3 (39.4% and 57.1%, respectively). The difference in OS was significant for both Group 3 (HR=0.40; 2-sided p=0.0004) and Group 2 (HR=0.31; 2-sided p=0.0016) compared with Group 1. Similarly, the median OS was increased from 12.6 months in the GC alone arm to 17.8 months in Group 3. The median OS was not evaluable in Group 2.

Overall, the interpretation of the OS results remained unchanged from those submitted at DBL2, in which the adjusted HR (95% CI) for the comparison of Group 3 with Group 1 was 0.36 (0.18, 0.72), and the adjusted HR (95% CI) for the comparison of Group 2 with Group 1 was 0.33 (0.15, 0.71). The overall number of deaths increased during the reporting period from 47 (21 in Group 1, 11 in Group 2, and 15 in Group 3) to 58 (25 in Group 1, 13 in Group 2, and 20 in Group 3).

To put these data in context, the median OS for Group 1 was compared to published literature for patients with locally recurrent/metastatic TNBC treated in a similar setting. In a Phase 3 study of iniparib plus GC versus GC alone in patients who had received 0 to 2 prior chemotherapy regimens for locally recurrent/metastatic disease, median OS among 258 patients treated with GC alone was 11.1 months (O'Shaughnessy, 2014). Similarly, in a recent study of combination chemotherapy for the first-line treatment of patients with metastatic TNBC, median OS was 12.1 months with GC (Yardley, 2018). This comparison suggests that the improvement in OS with trilaciclib + GC relative to GC alone is not due to an underperforming control arm, and that the control arm is representative of expected survival outcomes for this patient population.

Table 4: Summary of Overall Survival (ITT Analysis Set)

Category	Group 1 GC (Day 1+8) (N=34)	Group 2 GC + Trilaciclib (Day 1+8) (N=33)	Group 3 GC + Trilaciclib (Day 1/2+8/9) (N=35)	Group 2+3 (N=68)
Number of deaths, n (%)	25 (73.5%)	13 (39.4%)	20 (57.1%)	33 (48.5%)
Number of patients censored, n (%)	9 (26.5%)	20 (60.6%)	15 (42.9%)	35 (51.5%)
Overall survival (months) (95% CI)[a]				
25%	5.8 (2.8, 9.7)	9.4 (3.4, 19.6)	8.8 (6.0, 15.3)	8.8 (6.0, 14.0)
Median	12.6 (6.3, 15.6)	NE (10.2, NE)	17.8 (12.9, 32.7)	19.8 (14.0, NE)
75%	17.8 (12.8, 25.0)	NE (NE, NE)	32.7 (19.8, NE)	NE (32.7, NE)
Probability of being alive (95% CI) at[a]				
3 months	0.90 (0.73, 0.97)	0.97 (0.80, 1.00)	1.00 (1.00, 1.00)	0.99 (0.90, 1.00)
6 months	0.73 (0.53, 0.85)	0.81 (0.62, 0.91)	0.91 (0.75, 0.97)	0.86 (0.75, 0.93)
9 months	0.62 (0.42, 0.77)	0.77 (0.58, 0.88)	0.72 (0.53, 0.84)	0.74 (0.61, 0.83)
12 months	0.50 (0.31, 0.67)	0.69 (0.49, 0.83)	0.72 (0.53, 0.84)	0.71 (0.57, 0.80)
Comparison (treatment group versus Group 1)				
Adjusted HR (SE)[b]	NA	0.31 (0.111)	0.40 (0.125)	0.37 (0.101)
95% CI[b]	NA	0.15, 0.63	0.22, 0.74	0.21, 0.63
2-sided p-value[c]	NA	0.0016	0.0004	<0.0001
Duration on Study (months)				
Mean (SD)	9.7 (7.72)	16.1 (11.13)	15.9 (9.53)	16.0 (10.26)
Median	8.4	14.0	15.3	15.3
Min, Max	0.1, 25.7	1.3, 33.6	3.5, 33.7	1.3, 33.7

CI=confidence interval; DBL=database lock; GC=gemcitabine and carboplatin; HR=hazard ratio; ITT=intent-to-treat; Max=maximum; Min=minimum; N=total number of patients in each treatment group; n=subset (defined in table title) of total number of patients; NA=not applicable; NE=not evaluable; SD=standard deviation; SE=standard error.

[a] Calculated using the Kaplan-Meier method

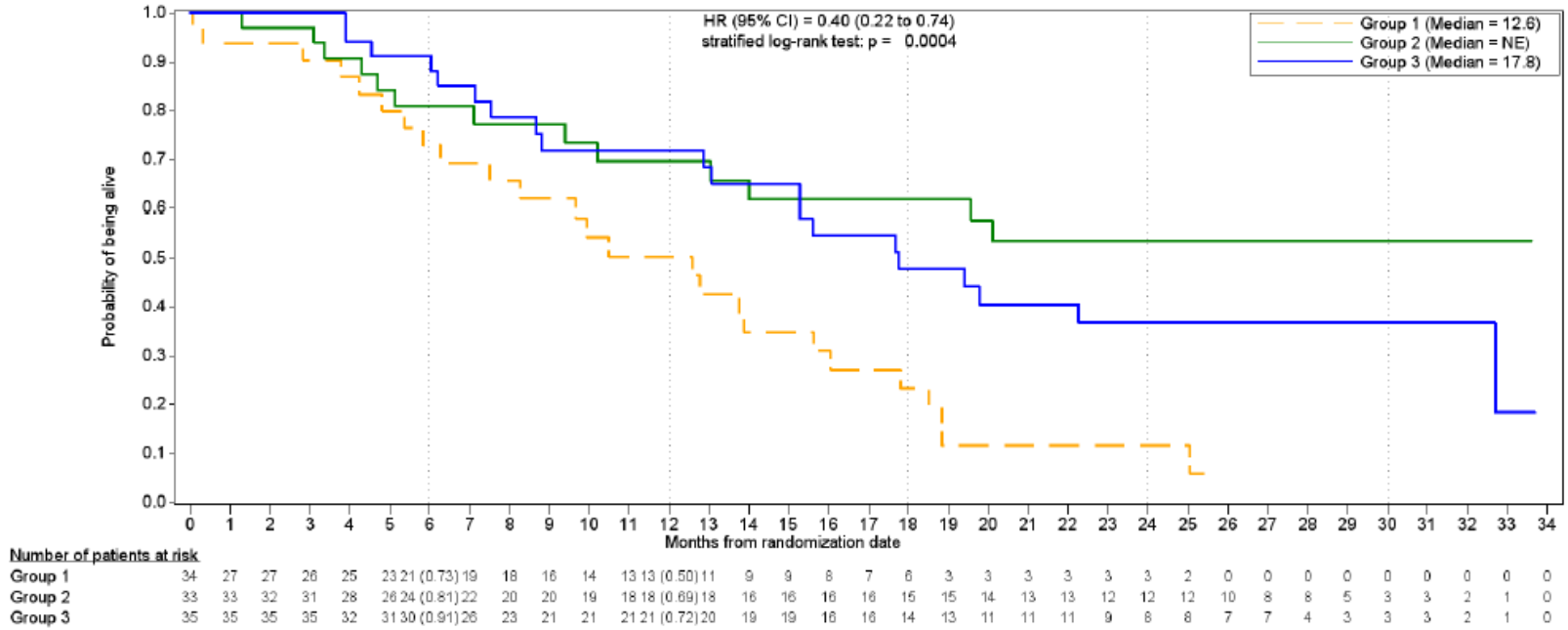
[b] The HR and its 95% CI were calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 or 2) and liver involvement.

[c] The p-value was calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 or 2) and liver involvement as the stratification factors.

Note: Unless otherwise specified, percentages were based on the number of patients in each treatment group.
Source: Table 14.2.9.1 (final DBL on 17 July 2020).

A listing of disease progression (derived assessments) or death for all enrolled patients is provided in Listing 16.2.13.4.1.

Figure 3: Overall Survival – Kaplan-Meier Curve (ITT Analysis Set)



CI=confidence interval; DBL=database lock; HR=hazard ratio; ITT=intent-to-treat; NE=not evaluable; OS=overall survival.
Note: The HR and its 95% CI comparing Groups 1 and 3 were calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 or 2) and liver involvement.
Note: P-value comparing Groups 1 and 3 was calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 or 2) and liver involvement as the stratification factors.
Source: Figure 14.2.9.2 (final DBL on 17 July 2020).

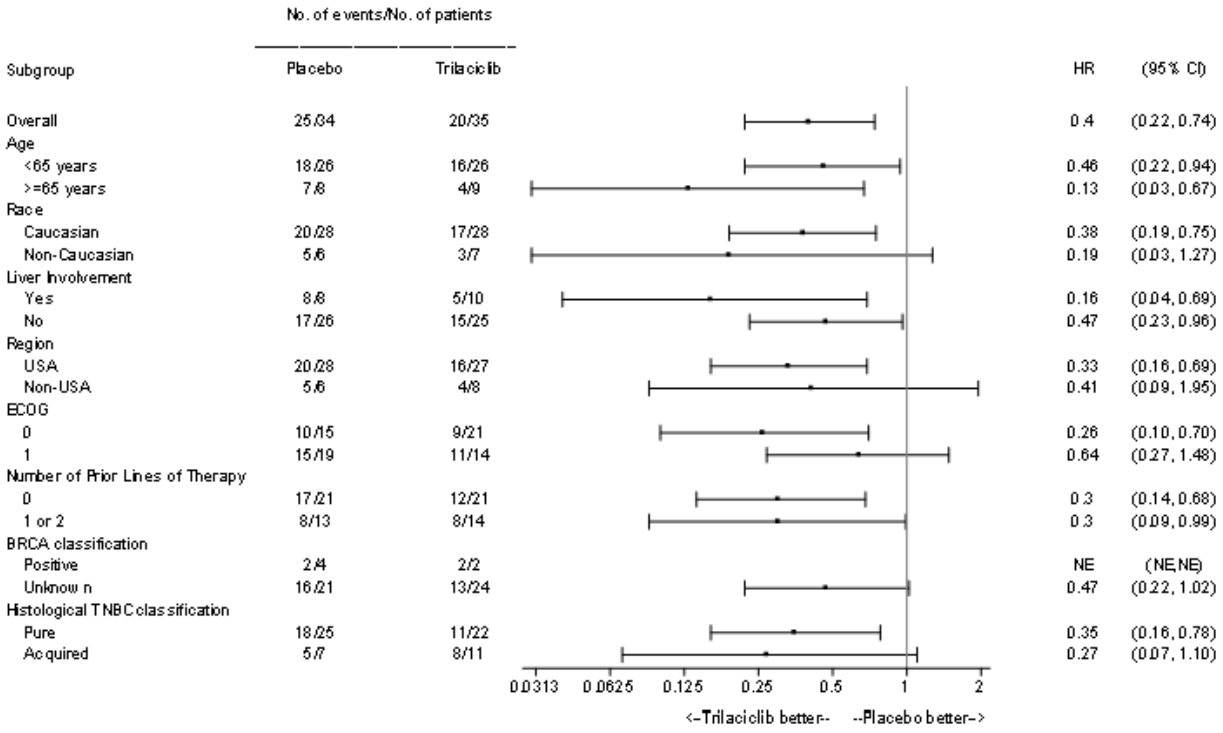
8.1.1. Overall Survival in Subgroups of Interest

Figure 4 presents a forest plot comparing OS by subgroups for Group 3 versus Group 1.

The favorable impact of trilaciclib on OS appeared to be generally consistent across all subgroups in the primary comparison of Group 3 to Group 1. Similar trends were seen in the individual comparison of Group 2 to Group 1. In addition, given the similar treatment effects observed between Group 2 and Group 3, subgroup analyses were performed using pooled trilaciclib groups versus Group 1 to assess the robustness of the effect and to increase statistical precision. Similar trends were observed in the analysis utilizing pooled trilaciclib data (Group 2 plus Group 3) in comparison to Group 1.

While the sample size in each subgroup was small, the hazard ratio was <1.0 for the majority of the subgroups, which suggests that patients in the subgroups evaluated have the potential to derive benefit from trilaciclib. The only exception to this was the BRCA positive subgroup where the HR was 1.41 for Group 2 and not evaluable for Group 3; however, the numbers in this subgroup were particularly small making it hard to draw any definitive conclusions (n=2 in Group 2 and n=2 in Group 3) (Table 14.2.9.16).

Figure 4: Overall Survival Hazard Ratio – Forest Plot (Group 3 Versus Group 1) (ITT Analysis Set)



CI=confidence interval; DBL=database lock; ECOG=Easter Cooperative Oncology Group; HR=hazard ratio; ITT=intent-to-treat; NE=not evaluable

Note: The HR and its 95% CI comparing Groups 3 and 1 are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.

Sources: Figure 14.2.9.3 (final DBL on 17 July 2020).

Results of the subgroup analyses for the primary and supportive comparison groups based on the End-of-Study analyses are summarized in Table 14.2.9.4 (<65 years old), Table 14.2.9.5 (≥65 years old), Table 14.2.9.6 (with liver involvement), Table 14.2.9.7 (without liver involvement), Table 14.2.9.8 (ECOG 0), Table 14.2.9.9 (ECOG 1), Table 14.2.9.10 (with 0 prior lines of therapy), Table 14.2.9.11 (with 1 or 2 prior lines of therapy), Table 14.2.9.12 (Caucasian), Table 14.2.9.13 (non-Caucasian), Table 14.2.9.14 (US), Table 14.2.9.15 (ex-US), Table 14.2.9.16 (positive BRCA), Table 14.2.9.17 (unknown BRCA), Table 14.2.9.18 (TNBC), and Table 14.2.9.19 (acquired TNBC).

9. EXPLORATORY EFFICACY

9.1. Genetic (DNA) and/or Expression (RNA/Protein) Biomarkers in Tumors and Blood

As of the final DBL, updated analyses evaluating ORR, PFS, and OS across treatment groups (Groups 1, 2, 3, or 2+3) for each CDK4/6 tumor subtype (ie, CDK4/6 independent, dependent, or indeterminate) did not reveal any consistent trends favoring one tumor subtype over another. Therefore, these data suggest that trilaciclib did not impair chemotherapy efficacy in tumors that are CDK4/6 indeterminate or dependent (O'Shaughnessy, 2020).

9.2. Immunologic Markers

Archival tumor tissue was collected at screening and retrospectively characterized by PD-L1 status via IHC and immune subtypes via RNA sequencing. Results of the ORR, PFS, and OS analysis by subtype are summarized in Table 5 and Table 6, respectively.

Expression of PD-L1 was considered positive in 49 of 85 (57.6%) tumor tissue samples, including 32 of 58 (55.2%) in the trilaciclib groups and 17 of 27 (63.0%) in the GC group (Table 5). This subgroup analysis indicated that the addition of trilaciclib prior to GC therapy enhanced ORR, PFS, and OS irrespective of PD-L1 status, although a larger benefit was observed in patients with PD-L1-positive TNBC.

Administering trilaciclib prior to GC also enhanced ORR, PFS and OS irrespective of immune status (Table 6) with some added PFS benefit in in the high immune-related gene expression subpopulations.

Table 5: Tumor Response, PFS, and OS According to PD-L1 Status

	PD-L1 Positive				PD-L1 Negative			
	Group 1	**Group 2**	**Group 3**	**Groups 2 and 3**	**Group 1**	**Group 2**	**Group 3**	**Groups 2 and 3**
Patients analyzed, n	17	16	16	32	10	10	16	26
ORR, n (%)	4 (23.5)	8 (50.0)	7 (43.8)	15 (46.9)	3 (30.0)	4 (40.0)	4 (25.0)	8 (30.8)
Median PFS, months (95% CI)	5.3 (3.3-NR)	7.9 (6.1-NR)	10.9 (6.2-NR)	9.7 (6.2-15.5)	9.2 (8.3-NR)	11.9 (8.8-NR)	9.0 (6.4-NR)	9.4 (6.5-14.6)
P value	-	0.492	0.075	0.149	-	0.376	0.488	0.943
HR (95% CI)	-	0.74 (0.3-1.7)	0.41 (0.2-1.1)	0.57 (0.3-1.2)	-	0.60 (0.2-1.9)	1.47 (0.5-4.3)	0.97 (0.4-2.5)
Median OS, months (95% CI)	10.5 (6.3-18.8)	20.1 (10.2-NR)	32.7 (15.3-NR)	32.7 (17.7-NR)	13.9 (12.6-NR)	NR (9.4-NR)	17.8 (12.9-NR)	17.8 (13.1-NR)
P value	-	0.037	0.01	0.004	-	0.077	0.198	0.093
HR (95% CI)	-	0.38 (0.2-1.0)	0.30 (0.1-0.8)	0.34 (0.2-0.7)	-	0.35 (0.1-1.2)	0.55 (0.2-1.4)	0.48 (0.2-1.2)

HR=hazard ratio; NR=not reached; ORR=objective response rate; OS=overall survival; PD-L1=programmed death ligand-1; PFS=progression-free survival.
Group 1: chemotherapy on Days 1 and 8; Group 2: trilaciclib and chemotherapy on Days 1 and 8; Group 3: trilaciclib alone on Days1 and 8 and with chemotherapy on Days 2 and 9. HR and p values are for comparisons between Group 2 and Group 1, Group 3 and Group 1, and between Groups 2 and 3 combined and Group 1.
Source: O'Shaughnessy, 2020

Table 6: Tumor Response, PFS, and OS According to Immune Subtypes

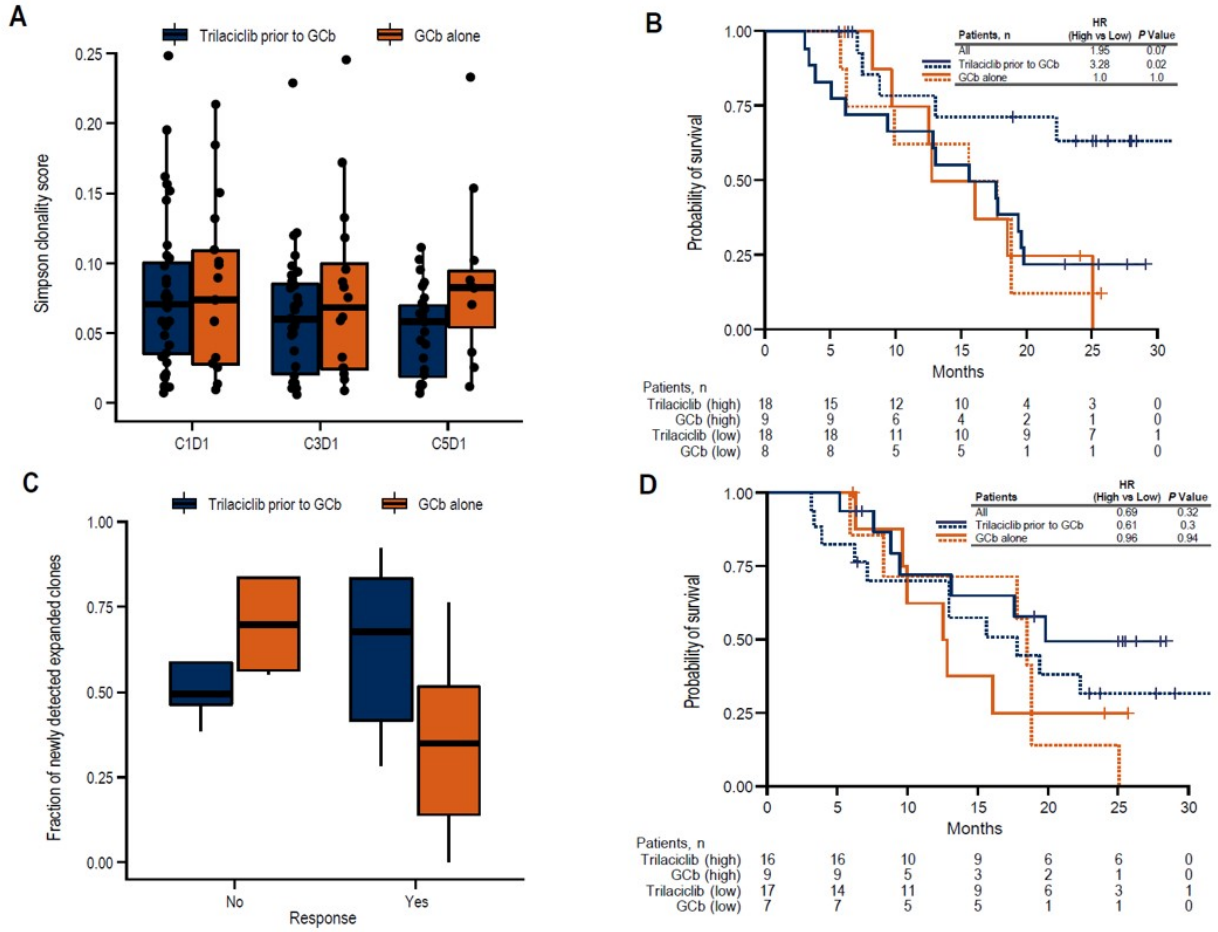
Subtype	High/Class 2				Low/Not Class 2			
	Group 1	**Group 2**	**Group 3**	**Groups 2 and 3**	**Group 1**	**Group 2**	**Group 3**	**Groups 2 and 3**
IFNγ signature, n	13	11	12	23	9	15	15	30
ORR, n (%)	5 (38.5)	7 (63.6)	6 (50.0)	13 (56.5)	2 (22.2)	5 (33.3)	6 (40.0)	11 (36.7)
Median PFS, months (95% CI)	5.7 (5.4-NR)	13.0 (11.3-NR)	9.0 (6.5-NR)	11.3 (7.3-NR)	8.3 (2.0-NR)	13.9 (3.9-NR)	7.9 (6.1-NR)	8.8 (6.1-14.6)
P value	-	0.0931	0.2797	0.0871	-	0.7513	0.846	0.7545
HR (95% CI)	-	0.40 (0.1-1.2)	0.59 (0.2-1.5)	0.49 (0.2-1.1)	-	0.85 (0.3-2.3)	0.90 (0.3-2.7)	0.87 (0.3-2.2)
Median OS, months (95% CI)	12.8 (9.7-NR)	20.1 (7.1-NR)	22.3 (17.8-NR)	22.3 (15.3-NR)	8.3 (6.3-NR)	15.3 (8.7-NR)	19.6 (10.2-NR)	15.6 (12.9-NR)
P value	-	0.0906	0.0257	0.0152	-	0.0207	0.0553	0.0168
HR (95% CI)	-	0.44 (0.2-1.2)	0.35 (0.1-0.9)	0.40 (0.2-0.9)	-	0.30 (0.1-0.9)	0.41 (0.2-1.1)	0.37 (0.2-0.9)
Expanded IFNγ signature, n	13	10	14	24	9	16	13	29
ORR, n (%)	5 (38.5)	6 (60.0)	6 (42.9)	12 (50.0)	2 (22.2)	5 (38.5)	7 (43.8)	12 (41.4)
Median PFS, months (95% CI)	5.7 (4.8-NR)	11.3 (8.8-NR)	9.0 (6.2-NR)	9.7 (7.3-20.1)	8.3 (2.0-NR)	13.9 (5.9-NR)	7.9 (6.1-NR)	9.4 (6.1-15.5)
P value	-	0.0924	0.2336	0.0765	-	0.9265	0.7972	0.8653
HR (95% CI)	-	0.39 (0.1-1.2)	0.56 (0.2-1.5)	0.47 (0.2-1.1)	-	1.0 (0.4-2.7)	1.2 (0.4-3.6)	1.1 (0.4-2.7)

Subtype	High/Class 2				Low/Not Class 2			
	Group 1	**Group 2**	**Group 3**	**Groups 2 and 3**	**Group 1**	**Group 2**	**Group 3**	**Groups 2 and 3**
Median OS, months (95% CI)	12.8 (9.7-NR)	NR (7.1-NR)	19.8 (15.3-NR)	20.1 (15.3-NR)	9.1 (6.3-NR)	17.7 (12.9-NR)	14.0 (10.2-NR)	15.6 (12.9-NR)
P value	-	0.0428	0.0692	0.0185	-	0.0643	0.0364	0.0226
HR (95% CI)	-	0.38 (0.1-1.0)	0.44 (0.2-1.1)	0.41 (0.2-0.9)	-	0.40 (0.1-1.1)	0.38 (0.1-1.0)	0.40 (0.2-0.9)
Six-class immune signature, n	10	17	18	35	12	9	9	18
ORR, n (%)	3 (30.0)	9 (52.9)	8 (44.4)	17 (48.6)	4 (33.3)	3 (33.3)	4 (44.4)	7 (38.9)
Median PFS, months (95% CI)	9.2 (5.4-HR)	8.8 (6.2-NR)	10.9 (6.5-NR)	10.9 (6.5-14.0)	5.4 (3.3-NR)	7.3 (1.2-NR)	9.7 (2.1-NR)	9.4 (5.9-15.6)
P value	-	0.5685	0.3952	0.4029	-	0.3799	0.9662	0.5126
HR (95% CI)	-	0.75 (0.3-2.0)	0.65 (0.2-1.8)	0.69 (0.3-1.7)	-	0.63 (0.2-1.8)	0.99 (0.4-2.7)	0.76 (0.3-1.8)
Median OS, months (95% CI)	12.8 (5.8-NR)	NR (13.0-NR)	22.3 (15.3-NR)	32.7 (15.3-NR)	10.2 (7.5-18.8)	13.1 (8.7-NR)	14.8 (9.4-HR)	13.1 (9.4-NR)
P value	-	0.1177	0.0822	0.0539	-	0.0971	0.1376	0.0609
HR (95% CI)	-	0.47 (0.2-1.2)	0.45 (0.2-1.1)	0.46 (0.2-1.0)	-	0.42 (0.1-1.2)	0.52 (0.2-1.3)	0.49 (0.2-1.0)

HR=hazard ratio; IFNγ=interferon-gamma signature; NR=not reached; ORR=objective response rate; OS=overall survival; PFS=progression-free survival.
Group 1: chemotherapy on Days 1 and 8; Group 2: trilaciclib and chemotherapy on Days 1 and 8; Group 3: trilaciclib alone on Days 1 and 8 and with chemotherapy on Days 2 and 9. HR and *P* values are for comparisons between Group 2 and Group 1, Group 3 and Group 1, and between Groups 2 and 3 combined and Group 1.
Class 2 was defined as IFN-γ dominant.
Not adjusted for multiplicity.
Source: O'Shaughnessy, 2020

To assess the effect of trilaciclib on the composition of lymphocyte subsets and clonal expansion, peripheral blood was collected and the TCR was evaluated. Simpson clonality significantly decreased over time in patients that received trilaciclib in addition to GC when compared to GC alone ($P_{interaction} = 0.012$; Figure 5A). Furthermore, when patients were stratified above or below median Simpson clonality, there was a trend for improved OS among patients with decreased peripheral clonality, with a statistically significant improvement among patients receiving trilaciclib (P = 0.02; Figure 5B).

Figure 5: TCR Clonality and Expansion



C=cycle; CR=complete response; D=day; GC=gemcitabine and carboplatin; HR=hazard ratio; PR=partial response; SD=stable disease.

Figures 2A and 2C show median values with 25% and 75% quartiles. For Kaplan–Meier estimates of probability of survival, patients were stratified by high (equal or above median, solid lines) and low (below median; dashed lines) Simpson clonality score (Figure 2B) and fraction of newly detected expanded clones (Figure 2D). HR indicates ratio of high relative to low. Values were calculated using Cox proportional hazards regression and the Wald test to determine statistical significance. Responders were defined as patients with a PR, CR, or SD ≥ 24 weeks.

Source: O'Shaughnessy, 2020

In addition to a decrease in Simpson clonality, responders receiving trilaciclib in Groups 2 and 3 had more newly detected expanded clones compared with responders receiving GC alone (P = 0.09; Figure 5C). Although not statistically significant, when patients were stratified above

or below the median fraction of newly detected expanded clones, OS was improved among patients with a higher fraction of newly detected expanded clones who received trilaciclib (Figure 5D). These data suggest trilaciclib enhances anti-tumor immunity through T cell activation leading to an anti-tumor response.

10. SAFETY EVALUATION

10.1. Extent of Exposure

The cumulative total exposures of trilaciclib, carboplatin, and gemcitabine for Patient 1111003 and Patient 1122001, who were still on study drug after DBL2 (28 June 2019), were 623 days and 707 days, respectively (Table 7).

As noted in Study G1T28-04 CSR, Patient 1111003 discontinued carboplatin due to an AE of platelet count decreased but continued receiving gemcitabine plus trilaciclib in the Treatment Phase. Patient 1111003 discontinued gemcitabine plus trilaciclib due to an AE of acute kidney injury. Additionally, Patient 1122001 had a skipped dose of trilaciclib and GC due to administrative reasons (see Study G1T28-04 CSR, Section 12.1.2.1). Patient 1122001 discontinued carboplatin and gemcitabine plus trilaciclib due to progressive disease (Listing 16.2.1.1.I).

Table 7: Total Exposure (Safety Analysis Set [Cumulative Data for Patients Who Were Still on Study Drug after DBL2])

Category	GC + Trilaciclib (Day 1+8)	
	Patient 1111003	**Patient 1122001**
Duration of exposure (days)	623	707
Number of cycles dosed	29	32
Relative dose intensity (%)		
Trilaciclib	88.0	98.5
Carboplatin	56.5	76.1
Gemcitabine	79.7	75.2
Cumulative actual dose		
Trilaciclib (mg/m^2)	12245.09	15122.76
Carboplatin (AUC)	67.00	102.50
Gemcitabine (mg/m^2)	47304.35	50663.65

AUC=area under the concentration-time curve; DBL= database lock; GC=gemcitabine and carboplatin.
Note: Relative dose intensity was defined as 100% times the actual dose intensity divided by the planned dose intensity. The planned dose intensity was defined as the cumulative planned dose through the study divided by (number of cycles×3 weeks).
Sources: Listing 16.2.5.4.F, Listing 16.2.5.5.F, and Listing 16.2.5.6.F (final DBL on 17 July 2020).

Cumulative administration of trilaciclib, carboplatin, and gemcitabine for the 2 patients who were still on study drug after DBL2 are provided in Listing 16.2.5.1.F, Listing 16.2.5.2.F, and Listing 16.2.5.3.F, respectively.

10.1.1. Dose Modifications

Between DBL2 and the final database lock, there were no additional dose interruptions, or dose reductions for Patient 1111003 or Patient 1122001. The final three treatment cycles for

Patient 1111003 were delivered every 21 days but did not include treatment on Day 8 with trilaciclib/gemcitabine. For Patient 1122001, the final 3 cycles of trilaciclib/gemcitabine included one skipped treatment (Day 8, Cycle 32) and 2 cycles delays (Listing 16.2.5.1.F, Listing 16.2.5.2.F, Listing 16.2.5.3.F, Listing 16.2.5.4.F, Listing 16.2.5.5.F, Listing 16.2.5.6.F).

10.2. Adverse Events

10.2.1. Treatment-emergent Adverse Events

The AEs occurring between DBL2 (28 June 2019) and the final database lock (17 July 2020; last patient last visit of date 28 February 2020) are summarized in Table 8. Adverse events were only collected up to 30 days after a patient's last dose of study drug. The corresponding patient listing for these AEs occurring since DBL2 is provided in Listing 16.2.7.1.I.

Patient 1122001 reported Grade 1 axillary pain and Grade 3 thrombocytopenia (reported by the investigator as related to carboplatin and gemcitabine and not related to trilaciclib). In addition, Patient 1131011, who completed treatment on 20 Feb 2019, reported a non-treatment emergent Grade 1 AE of nasal congestion. All other AEs were reported by Patient 1111003. Most of the AEs were either Grade 1 or Grade 2, and there were no Grade 4 AEs reported. The Grade 3 AEs included hypertension, anemia (multiple occurrences), fatigue, hematuria, nephrolithiasis, pleural effusion (multiple occurrences), platelet count decreased, hydronephrosis, acute kidney injury, urinary tract obstruction, dyspnea, and pulmonary oedema (Listing 16.2.7.1.I). Four Grade 3 occurrences of anemia were considered related to gemcitabine and trilaciclib; these AEs were considered not related to carboplatin as the patient had already discontinued carboplatin use. The Grade 3 AEs of platelet count decreased and pleural effusion (two occurrences) were reported by the investigator as related to gemcitabine and trilaciclib; these AEs were considered not related to carboplatin as the patient had already discontinued carboplatin use. The Grade 3 AE of pulmonary edema was reported by the investigator as related to trilaciclib, and not related to carboplatin (previously discontinued) or gemcitabine.

Table 8: AEs by SOC and PT (Safety Analysis Set [Incremental Data for Patients Who Were Still on Study Drug after DBL2])

PT	Group 2[a] Trilaciclib + GC (N=33)
Patients with any AE, n (%)	2
Abdominal pain	1
Abdominal pain lower	1
Acute kidney injury	1
Anaemia	1
Asthenia	1
Axillary pain	1
Back pain	1
Chills	1
Constipation	1
Diarrhoea	1
Diverticulum intestinal	1
Dyspnoea	1
Ecchymosis	1
Fatigue	1
Flank pain	1
Haematuria	1
Hydronephrosis	1
Hypertension	1
Hypocalcaemia	1
Nephrolithiasis	1
Pelvic neoplasm	1
Pericardial effusion	1
Platelet count decreased	1
Pleural effusion	1
Pneumonia	1
Pulmonary oedema	1
Pyrexia	1
Thrombocytopenia	1
Upper respiratory tract infection	1
Urinary tract infection	1

Table 8: AEs by SOC and PT (Safety Analysis Set [Incremental Data for Patients Who Were Still on Study Drug after DBL2])

PT	Group 2[a] Trilaciclib + GC (N=33)
Urinary tract obstruction	1
Vomiting	1

AE=adverse event; DBL=database lock; GC=gemcitabine and carboplatin; N=total number of patients in each treatment group; n=number of patients with an AE in each treatment group; PT=preferred term.

[a] Group 2 was trilaciclib + GC (Days 1+8). Group 1 (GC only [Days 1+8]) and Group 3 (trilaciclib + GC [Days 1/2+8/9]) are not presented, since no patients contributed to the safety follow-up in these groups.

Notes: A patient with multiple AE entries in the same PT was counted only once within a particular PT.
Source: Listing 16.2.7.1.I (final DBL on 17 July 2020).

10.2.2. Serious Adverse Events

A patient listing for SAEs occurring since DBL2 is provided in Listing 14.3.2.1.I. Full narratives for all SAEs are provided in Section 13.

Patient 1111003 experienced 3 SAEs between DBL2 and this End-of-Study analysis; these included Grade 3 hematuria, Grade 3 urinary tract obstruction, and Grade 3 pleural effusion. All 3 SAEs were reported as recovered/resolved. Only the pleural effusion SAE was reported by the investigator as related to trilaciclib, and also related to gemcitabine.

No other patients reported SAEs following DBL2.

10.2.3. Adverse Events Leading to Any Study Drug Discontinuation

Patient 1111003 experienced a Grade 3 AE of acute kidney injury (Study Day 617, Cycle 29 Day 15) that led to discontinuation of gemcitabine and trilaciclib. The event was not serious and was reported by the investigator as unrelated to trilaciclib (Listing 16.2.7.1.I).

No other AEs leading to discontinuation occurred between DBL2 and this End-of-Study analysis.

10.2.4. Narratives of Deaths, Other Serious Adverse Events, and Certain Other Significant Adverse Events

Narratives for deaths, SAEs, Grade 3 or 4 TEAEs considered related to trilaciclib, TEAEs leading to discontinuation of any study drug, injection site related TEAEs, phlebitis or thrombophlebitis TEAEs, pneumonitis/interstitial lung disease TEAEs, hepatotoxicity TEAEs, acute drug hypersensitivity reaction TEAEs, embolic or thrombotic events (venous) TEAEs, dose-limiting toxicities, patients who discontinued treatment due to reason of “lost to follow up”, and patients who had disease progression during study treatment or within 30 days of last dose have been provided with the G1T28-04 CSR for qualifying events as of the DCO date (28 June 2019) for DBL2. Since that date, events meeting the narrative category criteria were reported for two patients (Patient 1111003 and Patient 1122001) and these narratives have been updated (Section 13).

11. DISCUSSION AND OVERALL CONCLUSIONS

This was a global, multicenter, randomized, open-label, 3-arm, Phase 2 trial of the safety, efficacy, and PK of trilaciclib in patients with locally recurrent/metastatic TNBC receiving GC chemotherapy as first, second-, or third-line treatment.

A total of 142 patients with locally recurrent/metastatic TNBC were enrolled in this study and 102 were randomized 1:1:1 to GC alone or GC in combination with 2 different trilaciclib dosing schedules. Of those randomized, 4 were not treated, all of which were in Group 1.

The final DBL for Study G1T28-04 occurred on 17 July 2020 (with the last patient last visit date of 28 February 2020) and the results presented in this CSR addendum summarize the complete patient disposition, protocol deviations, subsequent anti-cancer therapy, and OS based on the End-of-Study analysis. In addition, details for AEs recorded between DBL2 and the final database lock are summarized.

In the End-of-Study analysis, all 98 patients (100%) discontinued study drug. Of the 2 patients in Group 2 who remained on study drug at the time of the G1T28-04 CSR (DBL2), 1 patient discontinued due to AE (acute kidney injury) and 1 patient discontinued due to disease progression. In addition, a total of 35 patients who remained in survival follow-up discontinued from the study between DBL2 and this End-of-Study analysis. These included 11 deaths (10 due to disease progression, 1 due to cardiopulmonary failure that occurred outside of protocol-specified reporting period, e.g., more than 30 days after the last dose of study treatment) and 24 Sponsor terminations.

The OS anti-tumor efficacy results presented previously were confirmed in the End-of-Study analysis and indicate that trilaciclib added to GC resulted in clinically meaningful improvements in OS. These results were observed in the context of a control group that is reflective of published literature for this patient population, and the benefit was observed for both trilaciclib groups (compared with the control group), thus representing internal reproducibility within a single clinical trial. In addition, the results are generally consistent across patient subgroups and were noted in the context of a manageable toxicity profile reflective of GC.

Subgroup analyses based on immunologic markers suggest that administering trilaciclib prior to GC benefits patients regardless of PD-L1 expression. Additionally, data from immune subtyping analyses and TCR immunosequencing suggest that administering trilaciclib prior to GC both preserved and enhanced immune system function potentially explaining the enhanced efficacy in patients that received trilaciclib prior to GC when compared to GC alone.

The additional safety data accumulated between DBL2 and final database lock was limited given that all but 2 patients had completed study treatment. The safety data accrued during this reporting period are consistent with and did not change the interpretation of the trilaciclib safety profile presented in the G1T28-04 CSR.

Conclusions

In Study G1T28-04, the updated OS data continued to favor both trilaciclib groups relative to the GC only group with clinically meaningful improvements in OS.

The initial set of safety data included in the G1T28-04 CSR was comprehensive. The limited safety data accrued since DBL2 are consistent with the trilaciclib safety profile reported in the G1T28-04 CSR.

12. REFERENCE LIST

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13. NARRATIVES OF DEATHS, OTHER SERIOUS AND CERTAIN OTHER SIGNIFICANT ADVERSE EVENTS

13.1. Patient 1111003

13.2. Patient 1122001

Study Number/Part:	G1T28-04 / Group 2
Investigator Number:	1111
Patient Number:	1111003
***NEW INFORMATION* presented in blue font**	
SAE / Case ID:	Platelet count decreased / 2019-1GU-000002 Hematuria / 2019-1GU-000035 Urinary tract obstruction / 2019-1GU-000038 Pleural effusion / 2019-1GU-000039
Death:	☒ N/A ☐ Due to Fatal AE on study or within 30 days of last dose ☐ Due to PD on study or within 30 days of last dose ☐ Due to Fatal AE after 30 days of last dose and related to study drug
AE(s) Leading to Discontinuation of Study Medication:	Platelet count decreased (discontinuation of carboplatin) Acute kidney injury (discontinuation of trilaciclib and gemcitabine)
Grade 3/4 AE related to trilaciclib	Neutrophil count decreased (5 events) Anaemia (1 event) Anaemia (1 event) Platelet count decreased Pulmonary oedema Acute kidney injury
Trilaciclib AE(s) of Special Interest	☐ N/A ☐ Injection site reaction ☐ Phlebitis/thrombophlebitis ☐ Pneumonitis/interstitial lung disease ☐ Hepatotoxicity ☐ Embolic and thrombotic events, venous ☒ Acute drug hypersensitivity reaction (Grade 1 face oedema)
Potential Hy's Law [defined as ALT and/or AST > ULN x3 in combination with ALP < ULN x2 and total bilirubin > ULN x2]	☐ Yes ☒ No
Discontinued Study Medication Due to "Lost to Follow-up"	☐ Yes ☒ No
Progression of Disease during Study Medication or Within 30 Days of Last Dose	☐ Yes ☒ No

Abbreviations: AE, adverse event; ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; DLT, dose-limiting toxicity; ID, identification; N/A, not applicable; PD, progressive disease; SAE, serious adverse event; ULN, upper limit of normal

Patient 1111003 is a 55-year-old white female from the United States who participated in study G1T28-04, Phase 2 Study of the Safety, Efficacy, and Pharmacokinetics of G1T28 in Patients with Metastatic Triple Negative Breast Cancer Receiving Gemcitabine and

Carboplatin Chemotherapy. The patient was enrolled on 12 Dec 2017 and randomised to Group 2 to receive trilaciclib (240 mg/m^2) in combination with gemcitabine (1000 mg/m^2) and carboplatin (AUC 2).

The patient's medical history included anxiety, hypothyroidism, congential cystic kidney disease, renal failure, and insomnia; all were ongoing at baseline. The patient's surgical history included biopsy of right axillary mass (22 Jan 2014), biopsy of right breast mass (22 Jan 2014), biopsy of right breast mass (01 Jul 2014), modified radical mastectomy of the right breast (08 Jul 2014), and core biopsy of the right neck supraclavicular lymph node (01 Dec 2017).

The patient never smoked.

The patient has a history of Stage IIIA, hormone receptor positive, HER2 negative breast cancer which was diagnosed on 22 Jan 2014. Following biopsy and a modified radical mastectomy of the right breast, the patient's diagnosis was confirmed as stage IIIA triple negative breast cancer on 08 Jul 2014. At the time of enrolment (12 Dec 2017), her disease had progressed to Stage IV.

Previous anticancer therapy includes doxorubicin and cyclophosphamide between 04 Mar 2014 and 16 Apr 2014 and paclitaxel between 30 Apr 2014 and 11 Jun 2014. Between 19 Aug 2014 and 08 Oct 2014, the patient received adjuvant radiation treatment to the chest wall and supraclavicular nodes.

The patient had a lymph node mestastasis as a target lesion (sum of diameters was 15 mm) and lung metastasis as a non-target lesion at study entry per investigator assessment performed on 11 Dec 2017. The patient did not have brain metastasis at baseline.

The patient received the first dose of trilaciclib (240 mg/m^2), along with gemcitabine (1000 mg/m^2) and carboplatin (AUC 2) on Days 1 and 8 of every 21-day cycle by intravenous (IV) infusion starting on 18 Dec 2017 (Cycle 1 Day 1, study Day 1). The last dose of study medication prior to the onset of face oedema was received on 16 Jan 2018 (Cycle 2 Day 8, study Day 30). The last dose of study medication prior to the onset of the first occurrence of neutrophil count decreased was received on 16 Jan 2018 (Cycle 2 Day 8, study Day 30). The last dose of study medication prior to the onset of anaemia was received on 26 Nov 2018 (Cycle 17 Day 1, study Day 344). The last dose of study medication prior to the onset of a serious adverse event (SAE) of decreased platelet count was received on 14 Jan 2019 (Cycle 19 Day 8, study Day 393). The last dose of study medication prior to the onset of events of anaemia, platelet count decreased, and pleural effusion was received on

22 Jul 2019 (Cycle 28 Day 1, study Day 582). The last dose of study medication prior to the onset of SAEs of hematuria and urinary tract obstruction. as well as the nonserious events of acute kidney injury and pulmonary oedema. was received on 12 Aug 2019 (Cycle 29 Day 1, study Day 603).

Other concomitant medications taken at the time of the non-serious adverse event AE of Grade 1 face oedema included lorazepam for anxiety, cholecalciferol and cyanocobalamin as vitamin supplements, levothyroxine for hypothyroidism, and lisinopril for hypertension.

On 17 Jan 2018 (Cycle 2 Day 9, study Day 31), 30 days after starting study medication and one day after the last dose of trilaciclib, gemcitabine, and carboplatin (Cycle 2 Day 8), the patient experienced a CTCAE Grade 1 hypersensitivity reaction of face oedema. The event was reported as not related to any of the study medications and remained ongoing at the end of the study period.

The patient's absolute neutrophil count (ANC), which was 5.01 x 10^9/L (Reference Range [RR]: 1.8-7.8 x 10^9/L) at screening, began to drop after the first cycle of treatment, reaching Grade 3 (0.86 x 10^9/L) after 15 days of treatment (02 Jan 2018; Cycle 1 Day 15, study Day 16); this was not considered clinically significant by the investigator. The patient's ANC continued to vary with cycles (see table below for laboratory findings around the Grade 3/4 events for neutrophil count decreased).

On 05 Feb 2018 (Cycle 3 Day 8, study Day 50), 49 days after starting study medication and seven days from the last dose of study medication (Cycle 3 Day 1), the patient experienced a non-serious adverse event (AE) of Grade 3 neutrophil count decreased (ANC = 0.84 x 10^9/L). No action was taken to treat the event, but Cycle 3 Day 8 study medications were skipped. The event resolved on 12 Feb 2018 (study Day 57) and study drug was resumed on 19 Feb 2018 (Cycle 4 Day 1, study Day 64). The investigator assessed the event as related to gemcitabine, carboplatin, and trilaciclib. Platelet and haemoglobin counts remained within the normal ranges between 05-12 Feb 2018.

On 13 Aug 2018 (Cycle 12 Day 8, study Day 239), 238 days after starting study medication and six days after the last dose of study medication (Cycle 12 Day 1), the patient experienced a non-serious AE of Grade 4 neutrophil count decreased (ANC 0.46 x 10^9/L). The Cycle 12 Day 8 dose of all three study medications was skipped. The event improved to Grade 2 on 20 Aug 2018 (study Day 246). The investigator assessed the event as related to gemcitabine, carboplatin, and trilaciclib.

On 27 Aug 2018 (Cycle 12 Day 22, study Day 253), 252 days after starting study medication and 20 days after the last dose (Cycle 12 Day 1), the patient experienced a non-serious AE of Grade 3 neutrophil count decreased (ANC 0.57 x 10^9/L). The Cycle 13 dose of study medication was delayed. The patient was treated with filgrastim 300 µg and the event resolved to Grade 0 on 04 Sep 2018 (study Day 261). Study Medication (Cycle 13 Day 1) was resumed that day. The investigator assessed the event as related to gemcitabine, carboplatin, and trilaciclib.

On 19 Nov 2018 (Cycle 16 Day 15, study Day 337), 336 days after starting study medication and seven days after the last dose of study medication (Cycle 16 Day 8), the patient experienced Grade 3 anaemia (hemoglobin 74 g/L, RR: 114-150) that was not reported as an AE as it was not considered clinically significant. The patient's haemoglobin returned to Grade 2 on 26 Nov 2018 (Cycle 17 Day 1, study Day 344) and study medication was administered.

On 03 Dec 2018 (Cycle 17 Day 8, study Day 351), 350 days after starting study medication and seven days after the last dose of study medication (Cycle 17 Day 1), the patient experienced a non-serious AE of Grade 3 anaemia (haemoglobin 66 g/L, RR: 114-150). The Cycle 17 Day 8 dose of all three study medications was skipped. Treatment included a red blood cell transfusion (2 units) given on 03 Dec 2018 (study Day 351). The event resolved on 10 Dec 2018, and study drug was resumed on the same day (Cycle 18 Day 1, study Day 358). The investigator assessed the event as related to gemcitabine, carboplatin, and trilaciclib.

On 17 Dec 2018 (Cycle 18 Day 8, study Day 365), 364 days after starting study medication and seven days from the last dose of study medication (Cycle 18 Day 1), the patient experienced a non-serious AE of Grade 3 neutrophil count decreased (ANC 0.6 x 10^9/L). Cycle 18 Day 8 dose of all three study medications was skipped and the event was considered related to gemcitabine, carboplatin, and trilaciclib. The event resolved to Grade 2 on 24 Dec 2018 (study Day 372).

On 31 Dec 2018 (Cycle 18 Day 22, study Day 379), 378 days after starting study medication and 21 days after the last dose (Cycle 18 Day 1), the patient experienced a non-serious AE of Grade 3 neutrophil count decreased (ANC 0.84 x 10^9/L). Study medications were delayed and the dose of carboplatin and gemcitabine was reduced at Cycle 19. The event, which was treated with concomitant medication, resolved on 07 Jan 2019 (Cycle 19 Day 1, study Day 386) and study medication administration was resumed. The investigator assessed the event as related to gemcitabine, carboplatin, and trilaciclib.

Concomitant medications taken at the time of the serious adverse event (SAE) event of Grade 4 decreased platelet count included: lorazepam for anxiety; diphenhydramine for insomnia; ondansetron for nausea; lisinopril for hypertension; paracetamol for general intermittent pain; palonosetron as prophylaxis for chemotherapy; lidocaine-prilocaine as prophylaxis for port care; rivaroxaban for pain in extremity thromboembolic event; colecalciferol, calcitriol, and cyanocobalamin for supplementation; and levothyroxine for hypothyroidism.

On 22 Jan 2019 (Cycle 19 Day 16, study Day 401), 400 days after the first dose of study medications and eight days after the last dose of study medications, the patient was hospitalized for platelet count decreased, Grade 4 in severity (platelet count 6 x 10^9/L [lowest value reported on that day], RR 143-382). On this same date, other laboratory results included hemoglobin 95 g/L (RR 114-150), white blood cell (WBC) count 2.67 x 10^9/L (RR 4-10.9), and ANC 1.63 x 10^9/L. Vital signs included blood pressure 105/72 mmHg, heart rate 80 beats per minute, respiratory rate 18 breaths per minute, and body temperature 36.5 °C. The investigator noted the patient reported "feeling off" but had no other symptoms or signs of bleeding. The patient was admitted for work-up of refractory thrombocytopenia. The Investigator noted that filgrastim (480 mcg) had been previously administered from 10-13 Jan 2019 (study Days 389-392) and pegfilgrastim (6000 mcg) had been administered on 15 Jan 2019 (study Day 394).

On 22 Jan 2019 (study Day 401), the patient was transfused with eight units of platelets, resulting in the patient's platelet count to increase to 47 x 10^9/L (note: CIOMS report indicated 2 units of platelets were administered, while the patient's case report form indicated 8 units were administered). On this day, the patient was started on losartan (12.5 mg, every day) for hypertension.

On 23 Jan 2019 (study Day 402), the patient received an additional transfusion of platelets. Laboratory results included hemoglobin 83 g/L, WBC count 2.10 x 10^9/L, platelet count 9 x 10^9/L, and ANC 1.22 x 10^9/L. On the same day, the event was reported to have improved to Grade 3 and the investigator considered the event to be a nonserious AE; the event of platelet count decreased resolved on 30 Jan 2019 (study Day 409). Carboplatin was permanently discontinued beginning on Cycle 20 Day 1(study Day 409) due to the decrease in platelet count.

On 24 Jan 2019 (study Day 403), laboratory results included haemoglobin 76 g/L, WBC count 3.44 x 10^9/L, platelet count 46 x 10^9/L, and ANC 2.30 x 10^9/L. On the same day, the

patient was discharged from the hospital. The Investigator confirmed no imaging was done during hospitalization.

At the time the patient experienced the SAE of Grade 4 decreased platelets, other ongoing AEs were Grade 2 nausea and fatigue; Grade 1 cough, face oedema, oedema peripheral, dyspnoea exertional, decreased appetite, alopecia, bone pain, dizziness, and peripheral sensory neuropathy.

During the study, the patient received growth factor on 14 occasions: filgrastim twice (300 and 480 µg) and pegfilgrastim 12 times (6000 µg). The first dose of growth factor was given on 27 Aug 2018 (Cycle 12 Day 21, study Day 253) and the last dose was administered on 18 Jun 2019 (Cycle 26 Day 9, study Day 548).

On 27 Jul 2019 (Cycle 28 Day 6), 587 days after starting study medication and five days after the last infusion of trilaciclib and gemcitabine, the patient experienced nonserious AEs of anaemia and platelet count decreased. At onset, the anaemia event was Grade 3, which was the maximum CTCAE grade during the event. At onset, the platelet count decreased event was Grade 1, with a maximum CTCAE grade during the event of Grade 3. Laboratory data are described below. Day 8 dosing was skipped in Cycle 28 and Cycle 29 due to the events. The patient received red blood cell (RBC) transfusions on 16 Aug 2019 (2 units; Cycle 29 Day 5, study Day 607), 30 Aug 2019 (2 units; Cycle 29 Day 19, study Day 621), and 08 Sep 2019 (1 unit; Cycle 29 Day 28, study Day 630) for the anaemia event. No treatment was administered for the platelet count decreased event. The event of platelet count decreased resolved on 26 Aug 2019 (study Day 617). The event of anaemia improved to Grade 1 on 09 Sep 2019 (study Day 631) and was ongoing at the time the patient discontinued from the study. The investigator considered both events to be related to trilaciclib and gemcitabine.

On 16 Aug 2019 (Cycle 29 Day 5), 607 days after starting study medication and five days after the last infusion of trilaciclib and gemcitabine, the patient experienced a serious AE of Grade 3 hematuria. The patient was referred to urgent care on this day for bright red hematuria with blood clots in the setting of polycystic kidney disease and rivaroxaban. She also complained of dyspnea with exertion. Vital signs included blood pressure 136/81 mmHg, heart rate 102 beats/minute, respiratory rate 18 breaths/minute and body temperature 36.7°C. Laboratory findings during the course of this event are presented in the table below. Urinalysis included bilirubin negative, leukocyte esterase negative, hemoglobin positive, protein 100, glucose and ketones negative, urine specific gravity 1.018 (RR 1.001 - 1.035), pH 6.0 (RR 4.5 - 8) and WBC 11-20/high power field (hpf). On the same day, a urine

and blood culture were negative with no growth. A computed tomography (CT) of thorax, abdomen, and pelvis was ordered which showed bilateral pleural effusion and rivaroxaban was discontinued on 16 Aug 2019. On an unknown date, another CT showed renal lesions throughout the kidneys. Treatment included 2 units of packed red blood cells [PRBC] for anemia, lactated ringers (2000 ml, IV, QD) until 17 Aug 2019 and acetaminophen (650 mg, PRN) from 17 to 18 Aug 2019.

On 18 Aug 2019 (study Day 609), clostridium difficile polymerase chain reaction (PCR) stool test and stool occult blood were negative. Additional laboratory results included prothrombin time (PT) 13.2 (RR 10.2 - 12.9), international normalized ratio (INR) 1.1 (RR 0.8 - 1.1) and activated partial thromboplastin time (aPTT) 30.2 (RR 25.1-36.5). On 19 Aug 2019, the patient was transfused with 2 units of PRBC. Post-transfusion laboratory results included hematocrit 26.8 %, hemoglobin 8.8 g/dL, WBC 2.5 K/µL, and platelets 68 K/µL. On 20 Aug 2019 (study Day 611), the patient was discharged from the hospital with home oxygen, and the event of hematuria was considered resolved. The investigator considered the event of hematuria to be unrelated to trilaciclib or gemcitabine.

On 16 Aug 2019 (Cycle 29 Day 5, study Day 607), the patient also experienced a nonserious AE of pleural effusion. At onset, the event was Grade 3, which was the maximum grade of the event. The investigator considered the nonserious event of pleural effusion as not related to study medication. On 19 Aug 2019 (study Day 610), a thoracentesis was performed, and 1.1 liters fluid was removed which was consistent with an exudative effusion per Light's criteria; pleural fluid culture was negative. The thoracentesis fluid cytology had no evidence of malignancy. On 27 Aug 2019 (study Day 618), a right thoracentesis was performed, and 900 mL of pleural fluid was drained. On the same date, the patient experienced another nonserious event of anemia (Grade 3) which the investigator considered unrelated to study treatment. She was treated with blood transfusion. Additional treatment included acetaminophen (325 mg, PRN) and tamsulosin (0.4 mg, daily).

On 04 Sep 2019 (Cycle 29 Day 23), 626 days after starting study medication and 23 days after the last infusion of trilaciclib and gemcitabine, the event of Grade 3 pleural effusion was reported as serious when the patient was hospitalized. On the same date, the patient had a thoracentesis in urgent care and presented to the hospital with worsening shortness of breath when lying down despite supplemental oxygen. The patient’s pulse oxygenation dropped from 95% to 81% and she was subsequently admitted for evaluation and management of shortness of breath. Additional vital signs included temperature 36.5°C, and respiratory rate increased from 20 to 32 breaths/minute. Upon physical examination there were diminished breath sounds at the bases. Laboratory findings during the course of this event are provided

in the table below. An echocardiogram showed normal left ventricle ejection fraction of 50-55%, an electrocardiogram (ECG) showed normal sinus rhythm with possible anterior infarct age undetermined, a bilateral lower and upper extremity venous doppler ultrasound showed no acute deep vein thrombosis, a chest x-ray showed developing small right pleural effusions with confluent airspace consolidation in the lung base, and a CT of the thorax without contrast showed moderate to large bilateral pleural effusions with confluent airspace consolidation in the lung base. The patient was treated with furosemide (40 mg, once, IV) and heparin (5000 units, as required, subcutaneous) for prophylaxis; the patient did not receive any steroids.

On 05 Sep 2019 (study Day 627), the patient underwent a Pleurx catheter placement in the right pleural space with successful collection of pleural fluid. Cytology results of a thoracentesis revealed mesothelial cells and macrophages and there was no evidence of malignancy. A follow up ECG showed sinus tachycardia; otherwise normal. A ventilation perfusion scan of the lung showed scinitigraphic findings when taken alone, consistent with a low probability for disease.

On 06 Sep 2019 (study Day 628), a chest x-ray showed small left pleural effusions with stable left retrocardiac opacity. On 07 Sep 2019, a chest x-ray showed increasing volume of left sided pleural effusion and dependent atelectasis. On 08 Sep 2019, the patient was transfused with 2 units of red blood cells. On 09 Sep 2019, the patient underwent a left side thoracentesis and 410 mL of fluid was drained. Cytology results of the pleural fluid revealed reactive mesothelial cells and macrophages and there was no evidence of malignancy. Pleural fluid culture with gram stain showed no growth, 2+ white blood cells, and no organisms were seen.

On 10 Sep 2019 (study Day 632), the investigator considered the serious event of pleural effusion resolved and reported the onset of a nonserious AE of Grade 3 pleural effusion on the same day. The serious and subsequent nonserious event of pleural effusion was attributed by the investigator as related to both trilaciclib and gemcitabine. On 11 Sep 2019 (study Day 633), the patient was discharged. The investigator reported the event of pleural effusion resolved on 09 Dec 2019 (study Day 722). The action taken with study medications was not applicable as the patient had discontinued further treatment on the study on 26 Aug 2019. Other events ongoing at the time of the onset of the SAE of pleural effusion included a non-serious AE of Grade 3 pulmonary oedema (onset 04 Sep 2019; event described below), fatigue; Grade 1 asthenia, platelet count decreased, urinary tract infection, acute kidney injury. The investigator considered the events of asthenia, platelet count decreased, and urinary tract infection to be related to trilaciclib and gemcitabine. The event of pulmonary

oedema was considered related to trilaciclib and not related to gemcitabine; the events of fatigue and acute kidney injury were considered by the investigator as unrelated to study medication.

On 24 Aug 2019 (study Day 615), the patient experienced a nonserious event of urinary tract obstruction with hydronephrosis (Grade 3) which was not related to study treatment. On 26 Aug 2019 (Cycle 29 Day 15), 617 days after starting study medication and 14 days after the last infusion of trilaciclib and gemcitabine, the patient was hospitalized for serious AE of urinary tract obstruction. On this same date, laboratory data confirmed a nonserious AE of Grade 3 acute kidney injury (AKI; creatinine 4.0 mg/dL). The patient reported she passed a kidney stone a couple days prior to admission and at her clinic appointment, the patient was noted to have had acute kidney injury due to an increased creatinine of 3.9 mg/dL. The patient was referred to urgent care where a renal ultrasound showed moderate left hydronephrosis likely congregation of cysts and the patient was subsequently admitted for the evaluation of nephrolithiasis and hydronephrosis. A chest x-ray showed development of small left pleural effusion and left basilar infiltration. A urinalysis revealed blood large, WBC 11-20 hpf, RBC 21-50 hpf, bacteria +2, and culture negative. A CT was not performed.

The investigator confirmed that hydronephrosis was not separate from nephrolithiasis but rather a symptom of her AKI and history of polycystic kidney disease. The patient was treated with sodium chloride 0.9% (1000 mL, IV, PRN) for the event of urinary tract obstruction; no treatment was administered for the event of AKI. Additional treatment included prochloperazine (10 mg, once) for intermittent nausea, and ranitidine (150 mg, BID) for indigestion prophylaxis.

On 28 Aug 2019 (study Day 619), a cystoscopy was performed and the Investigator confirmed a double J stent was successfully placed in the left ureter. On 31 Aug 2019 (Cycle 29 Day 20, study Day 622), the patient was discharged from the hospital, and the events of urinary tract obstruction and AKI were considered resolved. Additional treatment after discharge included: acetaminophen (650 mg, PRN) on 04 Sep 2019, acetaminophen (325 mg, once), clindamycin (900 mg, IV, once), fentanyl (25 mcg, IV, once), metoprolol (2.5 mg, IV, once) for hypertension, and sodium chloride 0.9% (1500 mL, IV, once) on 05 Sep 2019, and sodium chloride 0.9% (1000 mL, IV, once) on 06 Sep 2019.

The action taken with trilaciclib and gemcitabine for the event of urinary tract obstruction was not applicable as the study drugs had been permanently discontinued for the event of AKI on 26 Aug 2019. The investigator considered the event of AKI to be related to both

trilaciclib and gemcitabine; the event of urinary tract obstruction was considered unrelated to either of the study drugs.

At the time of the onset of the event of urinary tract obstruction, other nonserious AEs included Grade 1 urinary tract infection (onset 27 Jul 2019, ongoing at the time the patient discontinued the study), asthenia, diarrhea, diverticulum intestinal; Grade 2 dyspnea, abdominal pain, anemia, flank pain, pericardial effusion, pneumonia; Grade 3 fatigue, pleural effusion, nephrolithiasis, acute kidney injury. The investigator considered the events of urinary tract infection, asthenia, anemia, and pnuemonia related to trilaciclib and gemcitabine. All other events were considered not related to study medication.

On 04 Sep 2019 (study Day 626), the patient experienced a nonserious Grade 1 AKI which was ongoing at the time the patient discontinued from the study. The investigator considered the AKI not related to either trilaciclib or gemcitabine. No treatment was administered for the event.

On 04 Sep 2019 (Cycle 29 Day 23), 626 days after starting study medication and 22 days after the last infusion of trilaciclib and gemcitabine, the patient experienced a nonserious AE of pulmonary oedema. At onset, the event was Grade 3, which was the maximum CTCAE grade during the event. No action was taken with the study medications for the event. The patient received furosemide for the event: 40mg IV on 04 Sep 2019, 20mg IV BID on 05 Sep 2019 to 10 Sep 2019, and 20mg oral BID starting 11 Sep 2019 and reported as ongoing at the time of this report. The event was considered ongoing at the time the patient discontinued from the study. The investigator considered the event to be related to trilaciclib and unrelated to gemcitabine.

The patient completed 29 cycles of therapy. The patient received her last dose of carboplatin on 14 Jan 2019 (Cycle 19 Day 8, study Day 393). The patient received her last doses of trilaciclib and gemcitabine on 12 Aug 2019 (Cycle 29 Day 1, study Day 603). The patient discontinued further treatment with trilaciclib and gemcitabine due to an AE (Grade 3 AKI, onset 26 Aug 2019, study Day 617) and continued in the follow up phase of the study.

The investigator reported a partial response per RECIST 1.1 at the patient's last on-study disease assessment on 24 Jan 2020 (study Day 768). The location of the target lesion and non-target lesion were unchanged compared to screening. The sum of diameters was 0 mm (nadir sum of diameters); best response for the target lesion was complete response. The non-target lesion response at that date was non-CR/non-PD and no new lesion was identified.

No subsequent anticancer therapy was reported between the discontinuation of study treatment (26 Aug 2019) and the patient's discontinuation from the study (11 Feb 2020).

On 11 Feb 2020, 786 days after starting study medication, 394 days after the last dose of carboplatin, and 184 days after the last dose of trilaciclib and gemcitabine, the patient discontinued the study due to the Sponsor's termination of the study.

At the time of discontinuation from the study, the following events were ongoing: Grade 1 urinary tract infection, diarrhoea, ecchymosis (around right eye), diverticulum intestinal, AKI, anaemia, pelvic neoplasm (benign); Grade 2 pericardial effusion, pneumonia; and Grade 3 pulmonary oedema, dyspnoea. The investigator considered the following nonserious events to be related to gemcitabine and trilaciclib: urinary tract infection, ecchymosis, anaemia, and pneumonia. The nonserious event of pulmonary oedema was considered by the investigator to be related to trilaciclib and unrelated to gemcitabine. All other nonserious events were considered by the investigator to be unrelated to any study medication.

Laboratory findings:

Date	**ANC (10^9/L) (RR: 1.8-7.8 x 10^9/L)**	**CTCAE Grade**
12 Dec 2017 (Screening)	5.01	0
18 Dec 2017 (C1/D1, SD1)	3.48	0
26 Dec 2017 (C1/D8, SD9)	1.74	1
02 Jan 2018 (C1/D15, SD16)	0.86	3
08 Jan 2018 (C2/D1, SD22)	1.71	1
16 Jan 2018 (C2/D8, SD30)	1.64	1
22 Jan 2018 (C2/D15, SD36)	0.77	3
29 Jan 2018 (C3/D1, SD43)	1.24	2
05 Feb 2018 (C3/D8, SD50)	0.84	3
12 Feb 2018 (C3/D15, SD57)	1.72	1
30 Jul 2018 (C11/D15, SD225)	1.39	2
06 Aug 2018 (C12/D1, SD232)	1.17	2
13 Aug 2018 (C12/D8, SD239)	0.46	4
20 Aug 2018 (C12/D15, SD246)	1.133	2
27 Aug 2018 (C12/D22, SD253)	0.57	3
04 Sept 2018 (C13/D1, SD261)	2.27	0
10 Sept 2018 (C13/D8, SD267)	1.69	1
17 Sept 2018 (C13/D15, SD274)	3.66	0
03 Dec 2018 (C17/D8, SD351)	2.31	0

Date	ANC (10^9/L) (RR: 1.8-7.8 x 10^9/L)	CTCAE Grade
10 Dec 2018 (C18/D1, SD358)	1.46	2
17 Dec 2018 (C18/D8, SD365)	0.60	3
24 Dec 2018 (C18/D15, SD372)	1.06	2
31 Dec 2018 (C18/D22, SD379)	0.84	3
07 Jan 2019 (C19/D1, SD386)	1.04	2
14 Jan 2019 (C19/D8, SD393)	5.80	0
22 Jan 2019 (C19/D15, SD401 08:41)	1.92	0
22 Jan 2019 (Unscheduled, SD401 13:20)	1.63	1

C#/D#, cycle number/day number; CTCAE, Common Terminology Criteria for Adverse Events; SD, study day; RR, reference range

Laboratory Findings

Date (Visit)	Hgb (g/dL)	Platelets (10^9/L)	ANC (10^9/L)	WBC (10^9/L)	Potassium (mmol/L)	Sodium (mmol/L)	Chloride (mmol/L)	Albumin (g/dL)	Creatinine (mg/dL)	Total protein (g/dL)	BUN (mg/dL)	eGFR (mL/min/1.73m^2)
18 Dec 2017 (C1/D1)	13.7	202	3.48	5.85	4.2	140	102	4.0	1.1	7.2	20	ND
22 Jul 2019 (C28/D1)	9.4	200	1.86	3.91	3.9	142	110	4.0	2.0	6.5	33	ND
27 Jul 2019 (C28/D6)	7.8	131	5.80	6.67	4.4	139	108	3.6	2.0	5.9	42	ND
12 Aug 2019 (C29/D1)	9.6	117	1.72	3.82	4.3	141	110	4.1	2.0	6.4	40	ND
16 Aug 2019 (C29/D5)	7.6	90	4.83	5.19	5.0	138	109	3.6	1.9	5.8	49	ND
17 Aug 2019 (C29/D6)	9.1, 8.8, 10.2[a]	59	4.34	4.93	5.4	140	111	3.0	1.8	5.0	41	29
18 Aug 2019 (C29/D7)	8.4, 9.1[b]	43	2.25	3.12	4.6	137	110	2.7	2.0	4.9	36	26
19 Aug 2019 (C29/D8)	8.2	29	0.84	1.87	4.6	138	110	2.7	2.2	4.9	36	23
20 Aug 2019 (C29/D9)	8.4	63	1.59	2.8	4.7	140	109	2.9	2.0	5.2	39	26
23 Aug 2019 (C29/D12)	ND	ND	ND	ND	ND	ND	ND	ND	2.1	ND	ND	ND
26 Aug 2019 (C29/D15)	ND	ND	ND	ND	ND	ND	ND	ND	4.0	ND	ND	ND
28 Aug 2019 (C29/D17)	7.8	116	1.88	3.28	4.8	134	106	3.1	4.0	5.3	38	ND
29 Aug 2019	7.4	99	1.63	2.96	5.0	135	107	3.0	3.7	5.0	34	ND

Date (Visit)	Hgb (g/dL)	Platelets (10^9/L)	ANC (10^9/L)	WBC (10^9/L)	Potassium (mmol/L)	Sodium (mmol/L)	Chloride (mmol/L)	Albumin (g/dL)	Creatinine (mg/dL)	Total protein (g/dL)	BUN (mg/dL)	eGFR (mL/min/1.73m^2)
(C29/D18)												
30 Aug 2019 (C29/D19)	6.2, 9.0[c]	102	1.50	2.75	4.5	139	111	2.5	3.5	4.6	35	ND
31 Aug 2019 (C29/D20)	8.7	127	1.58	3.29	3.9	139	109	2.8	2.8	4.7	28	ND
04 Sep 2019 (C29/D23)	8.9	86	2.20	3.77	3.9	142	109	3.6	1.9	5.7	34	ND
06 Sep 2019 (C29/D25)	7.5	82	1.66	3.69	4.2	141	111	3.1	2.3	5.1	38	ND
08 Sep 2019 (C29/D27)	7.0	86	1.27	2.94	4.1	140	109	2.8	2.2	4.9	36	ND
09 Sep 2019 (C29/D28)	10.6	84	1.66	3.78	4.1	142	109	3.1	2.1	5.1	34	ND
10 Sep 2019 (C29/D29)	10.7	99	1.62	3.62	4.0	140	105	3.1	2.0	5.1	33	ND
17 Sep 2019 (Post Treatment Visit)	11.2	131	2.06	4.13	3.9	141	103	3.7	2.4	6.3	49	ND

Hgb reference range (RR): 11.4 – 15 g/dL
Platelets RR: 143 – 382 x 10^9/L
ANC RR: 1.8 – 7.8 x 10^9/L
WBC RR: 4 – 10.9 x 10^9/L
Potassium RR: 3.4 – 4.5 mmol/L
Sodium RR:134 – 145 mmol/L
Chloride RR: 96 – 107 mmol/L
Albumin RR: 3.5 – 5.2 g/dL
Creatinine RR: 0.5 – 1.0 mg/dL
Total Protein RR: 6.6 – 8.7 g/dL
Blood urea nitrogen (BUN) RR: 6 – 23 mg/dL
eGFR RR: ≥60
a Hemoglobin results reported at 00:57 (as reported in CIOMS 2019-1GU-000035), 05:13 (as reported in eCRF), and 13:23 (as reported in CIOMS 2019-1GU-000035),

Date (Visit)	Hgb (g/dL)	Platelets (10^9/L)	ANC (10^9/L)	WBC (10^9/L)	Potassium (mmol/L)	Sodium (mmol/L)	Chloride (mmol/L)	Albumin (g/dL)	Creatinine (mg/dL)	Total protein (g/dL)	BUN (mg/dL)	eGFR (mL/min/1.73m^2)

respectively, on 17 Aug 2019
b Hemoglobin results reported at 02:02 (as reported in eCRF) and 14:10 (as reported in CIOMS 2019-1GU-000035), respectively, on 18 Aug 2019
c Hemoglobin results reported at 03:44 and 14:03, respectively, on 30 Aug 2019
ANC, absolute neutrophil count; BUN, blood urea nitrogen; C#/D#, cycle number/day number; eCFR, electronic case report form; eGFR, estimated glomerular filtration rate; Hgb, hemoglobin; ND, not determined; RR, reference range; WB, white blood cell

Study Number/Part:	G1T28-04 / Group 2
Investigator Number:	1122
Patient Number:	1122001
***NEW INFORMATION* presented in blue font**	
SAE / Case ID:	Bacteraemia / 2019-1GU-000014
Death:	☒ N/A ☐ Due to Fatal AE on study or within 30 days of last dose ☐ Due to PD on study or within 30 days of last dose ☐ Due to Fatal AE after 30 days of last dose and related to study drug
AE(s) Leading to Discontinuation of Study Medication:	N/A
Grade 3/4 AE related to trilaciclib	N/A
Trilaciclib AE(s) of Special Interest	☐ N/A ☒ Injection site reaction (Grade 2 infusion related reaction) ☐ Phlebitis/thrombophlebitis ☐ Pneumonitis/interstitial lung disease ☐ Hepatotoxicity ☐ Embolic and thrombotic events, venous ☐ Acute drug hypersensitivity reaction
Potential Hy's Law [defined as ALT and/or AST > ULN x3 in combination with ALP < ULN x2 and total bilirubin > ULN x2]	☐ Yes ☒ No
Discontinued Study Medication Due to "Lost to Follow-up"	☐ Yes ☒ No
Progression of Disease during Study Medication or Within 30 Days of Last Dose	☒ Yes ☐ No
Abbreviations: AE, adverse event; N/A, not applicable; SAE, serious adverse event	

Patient 1122001 is a 42-year-old Asian female from the United States who participated in study G1T28-04, Phase 2 Study of the Safety, Efficacy, and Pharmacokinetics of G1T28 in Patients with Metastatic Triple Negative Breast Cancer Receiving Gemcitabine and Carboplatin Chemotherapy. The patient was enrolled on 18 Sep 2017 and randomized to Group 2 to receive trilaciclib (240 mg/m^2) with gemcitabine (1000 mg/m^2) and carboplatin (AUC 2).

That patient's medical history included cancer-related right-side pain, which was reported to be ongoing at baseline. The patient's surgical and medical procedure history included a right

breast needle biopsy (01 Aug 2017) and thoracic spine needle biopsy (12 Sep 2017) (both related to the breast cancer).

The patient never smoked.

The patient had a history of Stage IIIA triple negative breast cancer diagnosed on 01 Aug 2017. The patient had Stage IV disease at the time of enrollment (18 Sep 2017). The patient had received neither previous anti-cancer therapy nor previous radiation therapy.

The patient had breast metastases as target lesions (sum of diameters was 30 mm) and skin, lung, lymph node and bone metastases as nontarget lesions at study entry per investigator assessment of scans performed on 26 Sep 2017. It is unknown if the patient had brain metastases as no brain scans were reported.

Concomitant medication taken at the time of the non-serious adverse event (AE) of Grade 2 infusion related reaction (IRR) included triamcinolone for pruritus.

The patient received trilaciclib (240 mg/m^2) with gemcitabine (1000 mg/m^2) and carboplatin (AUC 2) on Days 1 and 8 of each 21-day cycle by intravenous (IV) infusion starting on 04 Oct 2017 (Cycle 1 Day 1, study Day 1). The last dose of study medication prior to the onset of the IRR was received on 27 Mar 2019 (Cycle 26 Day 8, study Day 540).

On 27 Mar 2019 (Cycle 26 Day 8), 540 days after the first dose of study medication, the patient experienced a non-serious Grade 2 IRR, which was treated with IV diphenhydramine and hydrocortisone. The AE was considered not related to trilaciclib or gemcitabine and related to carboplatin. On the same date, the patient also experienced chills that resolved that day and did not require any treatment. No action was taken with respect to study medication.

At the time of the AE of IRR, the following non-serious AEs were ongoing: Grade 2 depression (since 14 Feb 2018, study Day 134), which was considered not related to any study medication, and Grade 2 pruritus (since 20 Mar 2019), which was considered related to gemcitabine and not related to trilaciclib or carboplatin.

On 10 Apr 2019 (planned Cycle 27 Day 1), 554 days after the first dose of study medication 14 days after the last prior dose of study medication, the patient experienced the serious adverse event (SAE) of Grade 3 bacteraemia, which was considered an SAE due to hospitalization. The patient had been noted on 03 Apr 2019 to have experienced chills and had a scabbed sore on her lip which was considered possibly fever related. Blood cultures were reported to be positive for gram negative rods and the patient was advised to go to the hospital for admission. Vitals and urinalysis were not available. Other relevant laboratory

results included hemoglobin 7.5 g/dL (reference range (RR) 12 - 16), white blood cell count (WBC) 3.0 x 10^3/µL (RR 4.8 - 10.8), platelet count 129x10^3/µL (RR 130 - 400), absolute neutrophil count (ANC) 1.2 x 10^3/µL (RR 2 - 5), and monocyte percent 15% (RR 3 - 11). Study treatment was held on this day.

On 11 Apr 2019 (study Day 555), the patient presented to the emergency department and subsequently admitted to the hospital. A chest x-ray showed suspected mild/early lower lobe interstitial edema and added density in the medial left lower lobe suspicious for pneumonia. The Investigator confirmed that urinalysis was not available and procalcitonin was 100.41 ng/mL (RR ≤0.50). The investigator confirmed that the patient was not treated with granulocyte-colony stimulating factor (GCSF). The patient was treated once with IV cefepime 2 g and IV vancomycin 1000 mg and oral hydrocodone/paracetamol on 11 Apr 2019 (study Day 557); IV piperacillin-tazobactam 3.375 g q8h and vancomycin 500 mg BID on 11 and 12 Apr 2019 (study Days 556 and 557); oral paracetamol 650 mg from 11 to 20 Apr 2019 (study Days 555 to 564); IV cefepime 1 g q8h from 12 to 20 Apr 2019 (study Days 555 to 564); IV vancomycin 1000 mg once on 13 Apr 2019 (study Day 557); and IV vancomycin 750 mg BID on 14 Apr 2019 (study Day 558). On 14 Apr 2019, blood culture showed no growth at 5 days.

On 16 Apr 2019 (study Day 560), relevant laboratory tests revealed serum creatinine 0.47 mg/dL (RR 0.50 - 1.40), chloride 111 mmol/L (RR 100 - 108), anion gap 4 mmol/L (RR 8 - 16) and calculated osmolality 274 (RR 275 - 295).

On 18 Apr 2019 (study Day 562), the Mediport was removed and a new one was placed. It was determined that the source of the infection was from the patient's Mediport. Relevant laboratory tests on this day included creatinine 0.42 mg/dL, potassium 3.4 mmol/L (RR 3.5 - 5.3), CO_2-bicarbonate 20.4 mmol/L (RR 22.0 - 30.0), chloride 116 mmol/L, anion gap 2 mmol/L, calculated osmolality 273 and calcium 7.6 mg/dL (RR 8.4 - 10.2).

On 19 Apr 2019 (study Day 563), relevant laboratory tests included anion gap 6 mmol/L, WBC 3.4 k/µL (RR 4.5 - 11.0), red blood cells (RBC) 3.45 mil/µL (RR 4.00 - 5.20), hemoglobin 11.1 g/dL, hematocrit 32.5% (RR 36.0 - 46.0), red cell distribution width (RDW) 18.5% (RR 11.5 - 14.5) and monocytes relative 20% (RR 0 - 10).

On 20 Apr 2019 (study Day 564), the patient was discharged from the hospital with ciprofloxacin (500 mg, twice daily) for 14 days. Relevant laboratory tests at discharge included blood urea nitrogen (BUN) 6 mg/dL (RR 7 - 17), serum creatinine 0.47 mg/dL, anion gap 7 mmol/L, calculated osmolality 272, WBC 3.7 k/µL, RBC 3.68 mil/µL,

hemoglobin 11.5 g/dL, hematocrit 34.3%, RDW 18.6% and lymphocytes relative 50% (RR 24 - 44).

On 20 Apr 2019 (study Day 564), the event of bacteremia was considered resolved.

The SAE of bacteraemia was considered not related to any study medication but resulted in Cycle 27 dose delay for all study medications.

At the time of the SAE of bacteraemia, the following non-serious AE was ongoing: Grade 2 depression and pruritus.

The patient completed 33 cycles of therapy. The patient received her last dose of study medication on 28 Aug 2019 (study Day 694). Further treatment with study medication was discontinued on 25 Sep 2019 (study Day 722) due to disease progression and the patient continued in the follow up phase of the study.

The investigator reported disease progression per RECIST 1.1 at the patient's Post-treatment Visit disease assessment on 25 Sep 2019 (study Day 722). The location of target lesions and nontarget lesions were unchanged compared to screening. The sum of diameters was 24 mm (nadir sum of diameters was 17 mm observed at the patient's Cycle 9 assessment, study Day 349); best response for target lesions was partial response. Disease progression was determined with target lesions, and unequivocal progression of one of the four non-target lesions. No new lesions were observed.

Subsequent anticancer therapy with paclitaxel was initiated on 19 Dec 2019 and reported as ongoing at the time the patient discontinued from the study. No subsequent radiotherapy was reported.

On 20 Feb 2020, 899 days after starting study medication and 206 days after last dose of study medication, the patient discontinued the study due to the Sponsor's termination of the study.

14. TABLES, FIGURES AND LISTINGS

14.1. Tables and Figures

14.2. Listings

Table of Contents

Table 14.1.1.1
Patient disposition
All enrolled patients

Category	Group 1 (GC Day 1 and 8)	Group 2 (GC + Trilaciclib Day 1 and 8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9)	Group 2 and Group 3	Total
Enrolled patients [a]	NA	NA	NA	NA	142
Screen failure	NA	NA	NA	NA	40
Failure to Meet Eligibility Criteria [b]	NA	NA	NA	NA	40 (100.0%)
Patients randomized	34 (100.0%)	33 (100.0%)	35 (100.0%)	68 (100.0%)	102 (100.0%)
Patients randomized but not treated	4 (11.8%)	0	0	0	4 (3.9%)
Patients treated	30 (88.2%)	33 (100.0%)	35 (100.0%)	68 (100.0%)	98 (96.1%)

[a] Enrolled patients are those who signed informed consent and will only be represented in the Total column.
[b] The percentages are based on the total number of enrolled patients with screen failure.
[c] Only treated patients are included and the percentages are based on the total number of treated patients in each treatment group.
[d] This includes patients who withdrew consent for continuing treatment but agree to be continued for survival.
Note: Unless otherwise specified, percentages are based on the number of patients randomized.
NA = not available; eCRF = electronic case report form
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_disp.sas, Date/time of run: 11SEP2020:17:28

Table 14.1.1.1
Patient disposition
All enrolled patients

Category	Group 1 (GC Day 1 and 8)	Group 2 (GC + Trilaciclib Day 1 and 8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9)	Group 2 and Group 3	Total
Study drug disposition overall [c]					
Discontinued	30 (100.0%)	33 (100.0%)	35 (100.0%)	68 (100.0%)	98 (100.0%)
Disease progression	16 (53.3%)	16 (48.5%)	13 (37.1%)	29 (42.6%)	45 (45.9%)
Adverse event	9 (30.0%)	10 (30.3%)	9 (25.7%)	19 (27.9%)	28 (28.6%)
Non-compliance	0	0	0	0	0
Occurrence of pregnancy	0	0	0	0	0
Death	0	1 (3.0%)	1 (2.9%)	2 (2.9%)	2 (2.0%)
Discontinuation by investigator	1 (3.3%)	1 (3.0%)	7 (20.0%)	8 (11.8%)	9 (9.2%)
Patient withdrew consent [d]	2 (6.7%)	3 (9.1%)	4 (11.4%)	7 (10.3%)	9 (9.2%)
Lost to follow-up	0	0	0	0	0
Discontinued chemotherapy	0	1 (3.0%)	0	1 (1.5%)	1 (1.0%)
Other	2 (6.7%)	1 (3.0%)	1 (2.9%)	2 (2.9%)	4 (4.1%)

[a] Enrolled patients are those who signed informed consent and will only be represented in the Total column.
[b] The percentages are based on the total number of enrolled patients with screen failure.
[c] Only treated patients are included and the percentages are based on the total number of treated patients in each treatment group.
[d] This includes patients who withdrew consent for continuing treatment but agree to be continued for survival.
Note: Unless otherwise specified, percentages are based on the number of patients randomized.
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Table 14.1.1.1
Patient disposition
All enrolled patients

Category	Group 1 (GC Day 1 and 8)	Group 2 (GC + Trilaciclib Day 1 and 8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9)	Group 2 and Group 3	Total
Study drug disposition					
Trilaciclib [c]					
Discontinued	NA	33 (100.0%)	35 (100.0%)	68 (100.0%)	NA
Disease progression		16 (48.5%)	13 (37.1%)	29 (42.6%)	
Adverse event		10 (30.3%)	9 (25.7%)	19 (27.9%)	
Non-compliance		0	0	0	
Occurrence of pregnancy		0	0	0	
Death		1 (3.0%)	1 (2.9%)	2 (2.9%)	
Discontinuation by investigator		1 (3.0%)	7 (20.0%)	8 (11.8%)	
Patient withdrew consent [d]		3 (9.1%)	4 (11.4%)	7 (10.3%)	
Lost to follow-up		0	0	0	
Discontinued chemotherapy		1 (3.0%)	0	1 (1.5%)	
Other		1 (3.0%)	1 (2.9%)	2 (2.9%)	

[a] Enrolled patients are those who signed informed consent and will only be represented in the Total column.
[b] The percentages are based on the total number of enrolled patients with screen failure.
[c] Only treated patients are included and the percentages are based on the total number of treated patients in each treatment group.
[d] This includes patients who withdrew consent for continuing treatment but agree to be continued for survival.
Note: Unless otherwise specified, percentages are based on the number of patients randomized.
NA = not available; eCRF = electronic case report form
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Table 14.1.1.1
Patient disposition
All enrolled patients

Category	Group 1 (GC Day 1 and 8)	Group 2 (GC + Trilaciclib Day 1 and 8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9)	Group 2 and Group 3	Total
Study drug disposition					
Carboplatin [c]					
Discontinued	30 (100.0%)	33 (100.0%)	35 (100.0%)	68 (100.0%)	98 (100.0%)
Disease progression	15 (50.0%)	14 (42.4%)	13 (37.1%)	27 (39.7%)	42 (42.9%)
Adverse event	10 (33.3%)	13 (39.4%)	10 (28.6%)	23 (33.8%)	33 (33.7%)
Non-compliance	0	0	0	0	0
Occurrence of pregnancy	0	0	0	0	0
Death	0	1 (3.0%)	1 (2.9%)	2 (2.9%)	2 (2.0%)
Discontinuation by investigator	1 (3.3%)	1 (3.0%)	7 (20.0%)	8 (11.8%)	9 (9.2%)
Patient withdrew consent [d]	2 (6.7%)	3 (9.1%)	4 (11.4%)	7 (10.3%)	9 (9.2%)
Lost to follow-up	0	0	0	0	0
Discontinued chemotherapy	0	0	0	0	0
Other	2 (6.7%)	1 (3.0%)	0	1 (1.5%)	3 (3.1%)

[a] Enrolled patients are those who signed informed consent and will only be represented in the Total column.
[b] The percentages are based on the total number of enrolled patients with screen failure.
[c] Only treated patients are included and the percentages are based on the total number of treated patients in each treatment group.
[d] This includes patients who withdrew consent for continuing treatment but agree to be continued for survival.
Note: Unless otherwise specified, percentages are based on the number of patients randomized.
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Table 14.1.1.1
Patient disposition
All enrolled patients

Category	Group 1 (GC Day 1 and 8)	Group 2 (GC + Trilaciclib Day 1 and 8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9)	Group 2 and Group 3	Total
Study drug disposition					
Gemcitabine [c]					
Discontinued	30 (100.0%)	33 (100.0%)	35 (100.0%)	68 (100.0%)	98 (100.0%)
Disease progression	16 (53.3%)	16 (48.5%)	13 (37.1%)	29 (42.6%)	45 (45.9%)
Adverse event	8 (26.7%)	11 (33.3%)	9 (25.7%)	20 (29.4%)	28 (28.6%)
Non-compliance	0	0	0	0	0
Occurrence of pregnancy	0	0	0	0	0
Death	0	1 (3.0%)	1 (2.9%)	2 (2.9%)	2 (2.0%)
Discontinuation by investigator	2 (6.7%)	1 (3.0%)	7 (20.0%)	8 (11.8%)	10 (10.2%)
Patient withdrew consent [d]	2 (6.7%)	3 (9.1%)	4 (11.4%)	7 (10.3%)	9 (9.2%)
Lost to follow-up	0	0	0	0	0
Discontinued chemotherapy	0	0	0	0	0
Other	2 (6.7%)	1 (3.0%)	1 (2.9%)	2 (2.9%)	4 (4.1%)
Going into survival follow-up	25 (73.5%)	26 (78.8%)	30 (85.7%)	56 (82.4%)	81 (79.4%)

[a] Enrolled patients are those who signed informed consent and will only be represented in the Total column.
[b] The percentages are based on the total number of enrolled patients with screen failure.
[c] Only treated patients are included and the percentages are based on the total number of treated patients in each treatment group.
[d] This includes patients who withdrew consent for continuing treatment but agree to be continued for survival.
Note: Unless otherwise specified, percentages are based on the number of patients randomized.
NA = not available; eCRF = electronic case report form
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Table 14.1.1.1
Patient disposition
All enrolled patients

Category	Group 1 (GC Day 1 and 8)	Group 2 (GC + Trilaciclib Day 1 and 8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9)	Group 2 and Group 3	Total
Study disposition					
Discontinued	34 (100.0%)	33 (100.0%)	35 (100.0%)	68 (100.0%)	102 (100.0%)
Adverse event	0	0	0	0	0
Death	25 (73.5%)	13 (39.4%)	20 (57.1%)	33 (48.5%)	58 (56.9%)
Lost to follow-up	0	0	1 (2.9%)	1 (1.5%)	1 (<1%)
Patient withdrew consent	6 (17.6%)	4 (12.1%)	5 (14.3%)	9 (13.2%)	15 (14.7%)
Sponsor terminated study	2 (5.9%)	13 (39.4%)	9 (25.7%)	22 (32.4%)	24 (23.5%)
Other	1 (2.9%)	3 (9.1%)	0	3 (4.4%)	4 (3.9%)

[a] Enrolled patients are those who signed informed consent and will only be represented in the Total column.
[b] The percentages are based on the total number of enrolled patients with screen failure.
[c] Only treated patients are included and the percentages are based on the total number of treated patients in each treatment group.
[d] This includes patients who withdrew consent for continuing treatment but agree to be continued for survival.
Note: Unless otherwise specified, percentages are based on the number of patients randomized.
NA = not available; eCRF = electronic case report form
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Table 14.1.1.1
Patient disposition
All enrolled patients

Category	Group 1 (GC Day 1 and 8)	Group 2 (GC + Trilaciclib Day 1 and 8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9)	Group 2 and Group 3	Total
Primary reason for death					
Disease progression	21 (61.8%)	11 (33.3%)	19 (54.3%)	30 (44.1%)	51 (50.0%)
Adverse event	1 (2.9%)	0	0	0	1 (<1%)
Other	3 (8.8%)	2 (6.1%)	1 (2.9%)	3 (4.4%)	6 (5.9%)
Influenca A	1 (2.9%)	0	0	0	1 (<1%)
cardiopulmonary failure	1 (2.9%)	0	0	0	1 (<1%)
spoke with hospice house, info is not available in their records.	1 (2.9%)	0	0	0	1 (<1%)
unknown	0	0	1 (2.9%)	1 (1.5%)	1 (<1%)
unknown, death certificate not provided.	0	1 (3.0%)	0	1 (1.5%)	1 (<1%)
unknown, subject was treated by another Physician	0	1 (3.0%)	0	1 (1.5%)	1 (<1%)

[a] Enrolled patients are those who signed informed consent and will only be represented in the Total column.
[b] The percentages are based on the total number of enrolled patients with screen failure.
[c] Only treated patients are included and the percentages are based on the total number of treated patients in each treatment group.
[d] This includes patients who withdrew consent for continuing treatment but agree to be continued for survival.
Note: Unless otherwise specified, percentages are based on the number of patients randomized.
NA = not available; eCRF = electronic case report form
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Table 14.1.1.1
Patient disposition
All enrolled patients

Category	Group 1 (GC Day 1 and 8)	Group 2 (GC + Trilaciclib Day 1 and 8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9)	Group 2 and Group 3	Total
Duration on Study (months)					
n	34	33	35	68	102
Mean (SD)	9.7 (7.72)	16.1 (11.13)	15.9 (9.53)	16.0 (10.26)	13.9 (9.92)
Median	8.4	14.0	15.3	15.3	12.7
Min, Max	0.1, 25.7	1.3, 33.6	3.5, 33.7	1.3, 33.7	0.1, 33.7

[a] Enrolled patients are those who signed informed consent and will only be represented in the Total column.
[b] The percentages are based on the total number of enrolled patients with screen failure.
[c] Only treated patients are included and the percentages are based on the total number of treated patients in each treatment group.
[d] This includes patients who withdrew consent for continuing treatment but agree to be continued for survival.
Note: Unless otherwise specified, percentages are based on the number of patients randomized.
NA = not available; eCRF = electronic case report form
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Table 14.1.2.1
Protocol deviations
All randomized patients

Protocol deviations	Group 1 (GC Day 1 and 8) (N=34)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=33)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=35)	Group 2 and Group 3 (N=68)	Total (N=102)
Number of patients with at least one deviation	28 (82.4%)	31 (93.9%)	34 (97.1%)	65 (95.6%)	93 (91.2%)
Visit/Procedure Required	24 (70.6%)	25 (75.8%)	27 (77.1%)	52 (76.5%)	76 (74.5%)
Laboratory	16 (47.1%)	22 (66.7%)	19 (54.3%)	41 (60.3%)	57 (55.9%)
Visit Schedule	15 (44.1%)	21 (63.6%)	20 (57.1%)	41 (60.3%)	56 (54.9%)
Dosing	11 (32.4%)	20 (60.6%)	6 (17.1%)	26 (38.2%)	37 (36.3%)
Concomitant Medications	7 (20.6%)	7 (21.2%)	7 (20.0%)	14 (20.6%)	21 (20.6%)
Non-compliance	1 (2.9%)	4 (12.1%)	7 (20.0%)	11 (16.2%)	12 (11.8%)
Enrollment Criteria	4 (11.8%)	2 (6.1%)	2 (5.7%)	4 (5.9%)	8 (7.8%)
Informed Consent	3 (8.8%)	3 (9.1%)	0	3 (4.4%)	6 (5.9%)
Regulatory	0	2 (6.1%)	2 (5.7%)	4 (5.9%)	4 (3.9%)
Other	0	2 (6.1%)	0	2 (2.9%)	2 (2.0%)

Note: A patient with multiple entries in the same deviation is only counted once within a particular deviation.
Note: Number (%) of patients with deviations, sorted in decreasing order of frequency (by all treatment groups). If the frequencies tie, an alphabetic order will be applied.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
Note: Key deviations leading to exclusion are those key deviations which may affect the ability to assess the safety and efficacy of study drug.
PP = per-protocol
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_protdev.sas, Date/time of run: 11SEP2020:17:30

Table 14.1.2.1
Protocol deviations
All randomized patients

Protocol deviations	Group 1 (GC Day 1 and 8) (N=34)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=33)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=35)	Group 2 and Group 3 (N=68)	Total (N=102)
Number of patients with at least one key deviation	13 (38.2%)	16 (48.5%)	16 (45.7%)	32 (47.1%)	45 (44.1%)
Dosing	5 (14.7%)	6 (18.2%)	2 (5.7%)	8 (11.8%)	13 (12.7%)
Visit Schedule	2 (5.9%)	6 (18.2%)	5 (14.3%)	11 (16.2%)	13 (12.7%)
Non-compliance	1 (2.9%)	4 (12.1%)	6 (17.1%)	10 (14.7%)	11 (10.8%)
Concomitant Medications	4 (11.8%)	3 (9.1%)	3 (8.6%)	6 (8.8%)	10 (9.8%)
Laboratory	0	1 (3.0%)	6 (17.1%)	7 (10.3%)	7 (6.9%)
Enrollment Criteria	3 (8.8%)	1 (3.0%)	1 (2.9%)	2 (2.9%)	5 (4.9%)
Informed Consent	2 (5.9%)	3 (9.1%)	0	3 (4.4%)	5 (4.9%)
Regulatory	0	2 (6.1%)	2 (5.7%)	4 (5.9%)	4 (3.9%)
Other	0	1 (3.0%)	0	1 (1.5%)	1 (<1%)
Visit/Procedure Required	0	0	1 (2.9%)	1 (1.5%)	1 (<1%)

Note: A patient with multiple entries in the same deviation is only counted once within a particular deviation.
Note: Number (%) of patients with deviations, sorted in decreasing order of frequency (by all treatment groups). If the frequencies tie, an alphabetic order will be applied.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
Note: Key deviations leading to exclusion are those key deviations which may affect the ability to assess the safety and efficacy of study drug.
PP = per-protocol
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_protdev.sas, Date/time of run: 11SEP2020:17:30

Table 14.1.5.3
Summary of subsequent anticancer therapy
All randomized patients

ATC(chemical subgroup) Preferred Term	Group 1 (GC Day 1 and 8) (N=34)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=33)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=35)	Group 2 and Group 3 (N=68)
Patients with any subsequent anticancer therapy, n (%)	20 (58.8%)	20 (60.6%)	23 (65.7%)	43 (63.2%)
Subsequent Lines of Systemic Therapy				
1	11 (32.4%)	11 (33.3%)	8 (22.9%)	19 (27.9%)
2	3 (8.8%)	4 (12.1%)	5 (14.3%)	9 (13.2%)
3	2 (5.9%)	0	4 (11.4%)	4 (5.9%)
>=4	0	0	3 (8.6%)	3 (4.4%)
n	16	15	20	35
Mean (SD)	1 (0.7)	1 (0.5)	2 (1.2)	2 (1.1)
Median	1	1	2	1
Min, Max	1, 3	1, 2	1, 5	1, 5
PYRIMIDINE ANALOGUES	9 (26.5%)	8 (24.2%)	15 (42.9%)	23 (33.8%)
GEMCITABINE	6 (17.6%)	5 (15.2%)	11 (31.4%)	16 (23.5%)
GEMCITABINE	3 (8.8%)	4 (12.1%)	10 (28.6%)	14 (20.6%)
GEMCITABINE HYDROCHLORIDE	3 (8.8%)	1 (3.0%)	1 (2.9%)	2 (2.9%)
CAPECITABINE	4 (11.8%)	4 (12.1%)	8 (22.9%)	12 (17.6%)

Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
Note: Medications are coded using WHO DD version Sep2017.
Note: A patient with multiple anticancer therapy entries in the same ATC (PT) is only counted once within a particular ATC (PT).
Note: Number (%) of patients with subsequent anticancer therapy, sorted by ATC followed by PT in decreasing order of frequency (by all treatment groups). If the frequencies tie, an alphabetic order will be applied.
ATC = anatomical therapeutic classification; PT = preferred term; WHO DD = World Health Organization drug dictionary
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_cm.sas, Date/time of run: 11SEP2020:17:28

Table 14.1.5.3
Summary of subsequent anticancer therapy
All randomized patients

ATC(chemical subgroup) Preferred Term	Group 1 (GC Day 1 and 8) (N=34)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=33)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=35)	Group 2 and Group 3 (N=68)
OTHER ANTINEOPLASTIC AGENTS	8 (23.5%)	5 (15.2%)	11 (31.4%)	16 (23.5%)
ERIBULIN	7 (20.6%)	5 (15.2%)	6 (17.1%)	11 (16.2%)
ERIBULIN	4 (11.8%)	4 (12.1%)	4 (11.4%)	8 (11.8%)
ERIBULIN MESILATE	3 (8.8%)	2 (6.1%)	2 (5.7%)	4 (5.9%)
OLAPARIB	1 (2.9%)	0	4 (11.4%)	4 (5.9%)
ALPELISIB	0	0	1 (2.9%)	1 (1.5%)
OTHER ANTINEOPLASTIC AGENTS	1 (2.9%)	0	0	0
POLY ADP-RIBOSE POLYMERASE INHIBITOR	0	0	1 (2.9%)	1 (1.5%)
TAXANES	7 (20.6%)	6 (18.2%)	6 (17.1%)	12 (17.6%)
PACLITAXEL ALBUMIN	3 (8.8%)	2 (6.1%)	3 (8.6%)	5 (7.4%)
PACLITAXEL	2 (5.9%)	3 (9.1%)	2 (5.7%)	5 (7.4%)
DOCETAXEL	2 (5.9%)	1 (3.0%)	1 (2.9%)	2 (2.9%)
PLATINUM COMPOUNDS	5 (14.7%)	3 (9.1%)	10 (28.6%)	13 (19.1%)
CARBOPLATIN	5 (14.7%)	3 (9.1%)	10 (28.6%)	13 (19.1%)
MONOCLONAL ANTIBODIES	5 (14.7%)	5 (15.2%)	5 (14.3%)	10 (14.7%)
PEMBROLIZUMAB	4 (11.8%)	3 (9.1%)	2 (5.7%)	5 (7.4%)
ATEZOLIZUMAB	0	1 (3.0%)	2 (5.7%)	3 (4.4%)
NIVOLUMAB	1 (2.9%)	0	1 (2.9%)	1 (1.5%)
SACITUZUMAB GOVITECAN	0	1 (3.0%)	1 (2.9%)	2 (2.9%)

Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
Note: Medications are coded using WHO DD version Sep2017.
Note: A patient with multiple anticancer therapy entries in the same ATC (PT) is only counted once within a particular ATC (PT).
Note: Number (%) of patients with subsequent anticancer therapy, sorted by ATC followed by PT in decreasing order of frequency (by all treatment groups). If the frequencies tie, an alphabetic order will be applied.
ATC = anatomical therapeutic classification; PT = preferred term; WHO DD = World Health Organization drug dictionary
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_cm.sas, Date/time of run: 11SEP2020:17:28

Table 14.1.5.3
Summary of subsequent anticancer therapy
All randomized patients

ATC(chemical subgroup) Preferred Term	Group 1 (GC Day 1 and 8) (N=34)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=33)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=35)	Group 2 and Group 3 (N=68)
ANTHRACYCLINES AND RELATED SUBSTANCES	0	1 (3.0%)	8 (22.9%)	9 (13.2%)
DOXORUBICIN	0	1 (3.0%)	3 (8.6%)	4 (5.9%)
DOXORUBICIN	0	0	2 (5.7%)	2 (2.9%)
DOXORUBICIN HYDROCHLORIDE	0	1 (3.0%)	1 (2.9%)	2 (2.9%)
PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	0	0	3 (8.6%)	3 (4.4%)
EPIRUBICIN	0	0	1 (2.9%)	1 (1.5%)
EPIRUBICIN	0	0	1 (2.9%)	1 (1.5%)
LIPOSOMAL DOXORUBICIN HYDROCHLORIDE	0	0	1 (2.9%)	1 (1.5%)
INVESTIGATIONAL DRUG	2 (5.9%)	2 (6.1%)	5 (14.3%)	7 (10.3%)
INVESTIGATIONAL DRUG	2 (5.9%)	2 (6.1%)	5 (14.3%)	7 (10.3%)
VARIOUS	2 (5.9%)	4 (12.1%)	2 (5.7%)	6 (8.8%)
RADIOTHERAPY	2 (5.9%)	4 (12.1%)	2 (5.7%)	6 (8.8%)
VINCA ALKALOIDS AND ANALOGUES	0	1 (3.0%)	5 (14.3%)	6 (8.8%)
VINORELBINE	0	1 (3.0%)	5 (14.3%)	6 (8.8%)
VINORELBINE	0	1 (3.0%)	4 (11.4%)	5 (7.4%)
VINORELBINE TARTRATE	0	0	1 (2.9%)	1 (1.5%)

Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
Note: Medications are coded using WHO DD version Sep2017.
Note: A patient with multiple anticancer therapy entries in the same ATC (PT) is only counted once within a particular ATC (PT).
Note: Number (%) of patients with subsequent anticancer therapy, sorted by ATC followed by PT in decreasing order of frequency (by all treatment groups). If the frequencies tie, an alphabetic order will be applied.
ATC = anatomical therapeutic classification; PT = preferred term; WHO DD = World Health Organization drug dictionary
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_cm.sas, Date/time of run: 11SEP2020:17:28

Table 14.1.5.3
Summary of subsequent anticancer therapy
All randomized patients

ATC(chemical subgroup) Preferred Term	Group 1 (GC Day 1 and 8) (N=34)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=33)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=35)	Group 2 and Group 3 (N=68)
ALL OTHER THERAPEUTIC PRODUCTS	1 (2.9%)	1 (3.0%)	1 (2.9%)	2 (2.9%)
ALL OTHER THERAPEUTIC PRODUCTS	1 (2.9%)	1 (3.0%)	1 (2.9%)	2 (2.9%)
PROTEIN KINASE INHIBITORS	0	2 (6.1%)	1 (2.9%)	3 (4.4%)
CEDIRANIB	0	0	1 (2.9%)	1 (1.5%)
DABRAFENIB	0	1 (3.0%)	0	1 (1.5%)
EVEROLIMUS	0	1 (3.0%)	0	1 (1.5%)
TRAMETINIB	0	1 (3.0%)	0	1 (1.5%)
AROMATASE INHIBITORS	0	1 (3.0%)	1 (2.9%)	2 (2.9%)
ANASTROZOLE	0	0	1 (2.9%)	1 (1.5%)
LETROZOLE	0	1 (3.0%)	0	1 (1.5%)
NITROGEN MUSTARD ANALOGUES	0	1 (3.0%)	1 (2.9%)	2 (2.9%)
CYCLOPHOSPHAMIDE	0	1 (3.0%)	1 (2.9%)	2 (2.9%)
ANTINEOPLASTIC AGENTS	0	0	1 (2.9%)	1 (1.5%)
ENTINOSTAT	0	0	1 (2.9%)	1 (1.5%)

Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
Note: Medications are coded using WHO DD version Sep2017.
Note: A patient with multiple anticancer therapy entries in the same ATC (PT) is only counted once within a particular ATC (PT).
Note: Number (%) of patients with subsequent anticancer therapy, sorted by ATC followed by PT in decreasing order of frequency (by all treatment groups). If the frequencies tie, an alphabetic order will be applied.
ATC = anatomical therapeutic classification; PT = preferred term; WHO DD = World Health Organization drug dictionary
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Table 14.2.9.1
Summary of overall survival
Intent to treat analysis set

	Group 1 (GC Day 1 and 8) (N=34)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=33)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=35)	Group 2 and Group 3 (N=68)
Number of deaths, n (%)	25 (73.5%)	13 (39.4%)	20 (57.1%)	33 (48.5%)
Number of patients censored, n (%)	9 (26.5%)	20 (60.6%)	15 (42.9%)	35 (51.5%)
OS (months) (95% CI) [a]				
25%	5.8 (2.8, 9.7)	9.4 (3.4, 19.6)	8.8 (6.0, 15.3)	8.8 (6.0, 14.0)
Median	12.6 (6.3, 15.6)	NE (10.2, NE)	17.8 (12.9, 32.7)	19.8 (14.0, NE)
75%	17.8 (12.8, 25.0)	NE (NE, NE)	32.7 (19.8, NE)	NE (32.7, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.90 (0.73, 0.97)	0.97 (0.80, 1.00)	1.00 (1.00, 1.00)	0.99 (0.90, 1.00)
6 months	0.73 (0.53, 0.85)	0.81 (0.62, 0.91)	0.91 (0.75, 0.97)	0.86 (0.75, 0.93)
9 months	0.62 (0.42, 0.77)	0.77 (0.58, 0.88)	0.72 (0.53, 0.84)	0.74 (0.61, 0.83)
12 months	0.50 (0.31, 0.67)	0.69 (0.49, 0.83)	0.72 (0.53, 0.84)	0.71 (0.57, 0.80)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.31 (0.111)	0.40 (0.125)	0.37 (0.101)
95% CI [b]		0.15, 0.63	0.22, 0.74	0.21, 0.63
Two-sided p-value [c]		0.0016	0.0004	<0.0001

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.1
Summary of overall survival
Intent to treat analysis set

	Group 1 (GC Day 1 and 8) (N=34)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=33)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=35)	Group 2 and Group 3 (N=68)
Duration on Study (months)				
n	34	33	35	68
Mean (SD)	9.7 (7.72)	16.1 (11.13)	15.9 (9.53)	16.0 (10.26)
Median	8.4	14.0	15.3	15.3
Min, Max	0.1, 25.7	1.3, 33.6	3.5, 33.7	1.3, 33.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.4
Summary of overall survival
Intent to treat analysis set (patients < 65 years old)

	Group 1 (GC Day 1 and 8) (N=26)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=24)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=26)	Group 2 and Group 3 (N=50)
Number of deaths, n (%)	18 (69.2%)	9 (37.5%)	16 (61.5%)	25 (50.0%)
Number of patients censored, n (%)	8 (30.8%)	15 (62.5%)	10 (38.5%)	25 (50.0%)
OS (months) (95% CI) [a]				
25%	5.8 (2.8, 9.7)	7.1 (1.3, 13.0)	7.5 (3.9, 13.1)	7.1 (4.5, 10.2)
Median	12.6 (5.8, 16.0)	NE (7.1, NE)	17.7 (7.5, 32.7)	17.8 (9.4, NE)
75%	18.8 (12.6, NE)	NE (NE, NE)	32.7 (17.8, NE)	NE (32.7, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.95 (0.71, 0.99)	0.96 (0.74, 0.99)	1.00 (1.00, 1.00)	0.98 (0.87, 1.00)
6 months	0.71 (0.47, 0.86)	0.79 (0.56, 0.90)	0.88 (0.67, 0.96)	0.84 (0.70, 0.91)
9 months	0.62 (0.38, 0.79)	0.73 (0.50, 0.87)	0.62 (0.39, 0.78)	0.67 (0.51, 0.79)
12 months	0.52 (0.29, 0.70)	0.62 (0.38, 0.79)	0.62 (0.39, 0.78)	0.62 (0.45, 0.74)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.38 (0.162)	0.46 (0.169)	0.43 (0.138)
95% CI [b]		0.17, 0.88	0.22, 0.94	0.23, 0.80
Two-sided p-value [c]		0.0594	0.0141	0.0064

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.4
Summary of overall survival
Intent to treat analysis set (patients < 65 years old)

	Group 1 (GC Day 1 and 8) (N=26)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=24)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=26)	Group 2 and Group 3 (N=50)
Duration on Study (months)				
n	26	24	26	50
Mean (SD)	9.7 (7.98)	15.2 (11.44)	14.8 (9.98)	15.0 (10.60)
Median	8.0	9.8	10.9	9.8
Min, Max	0.1, 25.7	1.3, 33.6	3.5, 33.7	1.3, 33.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.5
Summary of overall survival
Intent to treat analysis set (patients >= 65 years old)

	Group 1 (GC Day 1 and 8) (N=8)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=9)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=9)	Group 2 and Group 3 (N=18)
Number of deaths, n (%)	7 (87.5%)	4 (44.4%)	4 (44.4%)	8 (44.4%)
Number of patients censored, n (%)	1 (12.5%)	5 (55.6%)	5 (55.6%)	10 (55.6%)
OS (months) (95% CI) [a]				
25%	4.3 (0.1, 15.6)	16.8 (4.3, NE)	15.4 (12.9, NE)	15.6 (4.3, 19.8)
Median	10.5 (0.1, 17.8)	20.1 (4.3, NE)	19.8 (12.9, NE)	20.1 (15.3, NE)
75%	17.8 (8.3, 18.5)	NE (19.6, NE)	NE (15.6, NE)	NE (20.1, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.75 (0.31, 0.93)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
6 months	0.75 (0.31, 0.93)	0.88 (0.39, 0.98)	1.00 (1.00, 1.00)	0.94 (0.65, 0.99)
9 months	0.60 (0.20, 0.85)	0.88 (0.39, 0.98)	1.00 (1.00, 1.00)	0.94 (0.65, 0.99)
12 months	0.45 (0.11, 0.75)	0.88 (0.39, 0.98)	1.00 (1.00, 1.00)	0.94 (0.65, 0.99)

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.5
Summary of overall survival
Intent to treat analysis set (patients >= 65 years old)

	Group 1 (GC Day 1 and 8) (N=8)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=9)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=9)	Group 2 and Group 3 (N=18)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.15 (0.128)	0.13 (0.109)	0.14 (0.091)
95% CI [b]		0.03, 0.78	0.03, 0.67	0.04, 0.50
Two-sided p-value [c]		0.0238	0.0198	0.0020

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.5
Summary of overall survival
Intent to treat analysis set (patients >= 65 years old)

	Group 1 (GC Day 1 and 8) (N=8)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=9)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=9)	Group 2 and Group 3 (N=18)
Duration on Study (months)				
n	8	9	9	18
Mean (SD)	9.6 (7.34)	18.6 (10.49)	19.1 (7.71)	18.8 (8.93)
Median	9.4	19.6	19.0	19.3
Min, Max	0.1, 18.5	2.5, 32.8	5.7, 28.0	2.5, 32.8

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.6
Summary of overall survival
Intent to treat analysis set (patients with liver involvement)

	Group 1 (GC Day 1 and 8) (N=8)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=10)	Group 2 and Group 3 (N=18)
Number of deaths, n (%)	8 (100.0%)	6 (75.0%)	5 (50.0%)	11 (61.1%)
Number of patients censored, n (%)	0	2 (25.0%)	5 (50.0%)	7 (38.9%)
OS (months) (95% CI) [a]				
25%	1.6 (0.1, 5.8)	4.3 (3.1, 14.0)	6.0 (3.9, 7.1)	5.1 (3.1, 7.1)
Median	4.8 (0.1, 13.8)	10.2 (3.1, 20.1)	7.1 (3.9, NE)	10.2 (5.1, NE)
75%	11.0 (2.8, 18.5)	20.1 (5.1, NE)	NE (7.1, NE)	NE (10.2, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.63 (0.23, 0.86)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
6 months	0.38 (0.09, 0.67)	0.63 (0.23, 0.86)	0.80 (0.41, 0.95)	0.72 (0.46, 0.87)
9 months	0.25 (0.04, 0.56)	0.63 (0.23, 0.86)	0.48 (0.16, 0.74)	0.54 (0.29, 0.74)
12 months	0.25 (0.04, 0.56)	0.47 (0.12, 0.76)	0.48 (0.16, 0.74)	0.47 (0.22, 0.68)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.46 (0.297)	0.16 (0.118)	0.31 (0.170)
95% CI [b]		0.13, 1.63	0.04, 0.69	0.11, 0.91
Two-sided p-value [c]		0.3363	0.0098	0.0335

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.6
Summary of overall survival
Intent to treat analysis set (patients with liver involvement)

	Group 1 (GC Day 1 and 8) (N=8)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=8)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=10)	Group 2 and Group 3 (N=18)
Duration on Study (months)				
n	8	8	10	18
Mean (SD)	6.7 (6.55)	11.7 (9.88)	11.7 (9.19)	11.7 (9.21)
Median	4.8	8.3	6.9	6.9
Min, Max	0.1, 18.5	3.1, 31.5	3.9, 27.9	3.1, 31.5

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.7
Summary of overall survival
Intent to treat analysis set (patients without liver involvement)

	Group 1 (GC Day 1 and 8) (N=26)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=25)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=25)	Group 2 and Group 3 (N=50)
Number of deaths, n (%)	17 (65.4%)	7 (28.0%)	15 (60.0%)	22 (44.0%)
Number of patients censored, n (%)	9 (34.6%)	18 (72.0%)	10 (40.0%)	28 (56.0%)
OS (months) (95% CI) [a]				
25%	9.7 (4.2, 12.6)	13.0 (1.3, NE)	13.1 (3.9, 17.7)	13.0 (7.5, 17.8)
Median	12.8 (9.7, 17.8)	NE (13.0, NE)	19.4 (13.1, 32.7)	22.3 (15.6, NE)
75%	18.8 (13.9, NE)	NE (NE, NE)	32.7 (19.4, NE)	NE (32.7, NE)
Probability of being alive (95% CI) at [a]				
3 months	1.00 (1.00, 1.00)	0.96 (0.75, 0.99)	1.00 (1.00, 1.00)	0.98 (0.87, 1.00)
6 months	0.86 (0.62, 0.95)	0.87 (0.65, 0.96)	0.96 (0.74, 0.99)	0.92 (0.79, 0.97)
9 months	0.76 (0.51, 0.89)	0.82 (0.60, 0.93)	0.82 (0.59, 0.93)	0.82 (0.67, 0.91)
12 months	0.59 (0.35, 0.77)	0.77 (0.53, 0.90)	0.82 (0.59, 0.93)	0.80 (0.64, 0.89)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.26 (0.120)	0.47 (0.172)	0.37 (0.124)
95% CI [b]		0.11, 0.64	0.23, 0.96	0.19, 0.72
Two-sided p-value [c]		0.0014	0.0106	0.0006

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.7
Summary of overall survival
Intent to treat analysis set (patients without liver involvement)

	Group 1 (GC Day 1 and 8) (N=26)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=25)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=25)	Group 2 and Group 3 (N=50)
Duration on Study (months)				
n	26	25	25	50
Mean (SD)	10.6 (7.93)	17.5 (11.33)	17.6 (9.29)	17.6 (10.25)
Median	9.8	19.6	17.7	17.7
Min, Max	0.1, 25.7	1.3, 33.6	3.5, 33.7	1.3, 33.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.8
Summary of overall survival
Intent to treat analysis set (patients with ECOG 0)

	Group 1 (GC Day 1 and 8) (N=15)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=17)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=21)	Group 2 and Group 3 (N=38)
Number of deaths, n (%)	10 (66.7%)	6 (35.3%)	9 (42.9%)	15 (39.5%)
Number of patients censored, n (%)	5 (33.3%)	11 (64.7%)	12 (57.1%)	23 (60.5%)
OS (months) (95% CI) [a]				
25%	4.8 (3.8, 9.9)	13.0 (4.3, NE)	15.3 (3.9, 19.4)	15.3 (5.1, 19.6)
Median	9.9 (4.2, 16.0)	NE (13.0, NE)	22.3 (15.3, NE)	NE (17.7, NE)
75%	16.0 (6.3, NE)	NE (NE, NE)	NE (22.3, NE)	NE (NE, NE)
Probability of being alive (95% CI) at [a]				
3 months	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
6 months	0.64 (0.30, 0.85)	0.88 (0.61, 0.97)	0.90 (0.66, 0.97)	0.89 (0.74, 0.96)
9 months	0.55 (0.23, 0.78)	0.88 (0.61, 0.97)	0.85 (0.60, 0.95)	0.86 (0.70, 0.94)
12 months	0.45 (0.17, 0.71)	0.81 (0.51, 0.93)	0.85 (0.60, 0.95)	0.83 (0.66, 0.92)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.16 (0.095)	0.26 (0.131)	0.22 (0.096)
95% CI [b]		0.05, 0.51	0.10, 0.70	0.09, 0.52
Two-sided p-value [c]		0.0021	0.0027	0.0001

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.8
Summary of overall survival
Intent to treat analysis set (patients with ECOG 0)

	Group 1 (GC Day 1 and 8) (N=15)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=17)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=21)	Group 2 and Group 3 (N=38)
Duration on Study (months)				
n	15	17	21	38
Mean (SD)	8.5 (8.44)	19.3 (11.13)	16.7 (10.17)	17.9 (10.54)
Median	5.8	20.1	17.7	18.6
Min, Max	0.1, 25.7	4.3, 33.6	3.5, 33.7	3.5, 33.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.9
Summary of overall survival
Intent to treat analysis set (patients with ECOG 1)

	Group 1 (GC Day 1 and 8) (N=19)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=16)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=14)	Group 2 and Group 3 (N=30)
Number of deaths, n (%)	15 (78.9%)	7 (43.8%)	11 (78.6%)	18 (60.0%)
Number of patients censored, n (%)	4 (21.1%)	9 (56.3%)	3 (21.4%)	12 (40.0%)
OS (months) (95% CI) [a]				
25%	7.5 (0.1, 10.5)	4.7 (1.3, 14.0)	7.5 (3.9, 12.9)	7.1 (3.4, 9.4)
Median	13.8 (7.5, 17.8)	14.0 (3.4, NE)	13.0 (7.1, 32.7)	13.1 (7.5, 32.7)
75%	18.5 (13.8, NE)	NE (14.0, NE)	32.7 (12.9, 32.7)	32.7 (15.6, 32.7)
Probability of being alive (95% CI) at [a]				
3 months	0.84 (0.57, 0.94)	0.94 (0.63, 0.99)	1.00 (1.00, 1.00)	0.97 (0.79, 1.00)
6 months	0.78 (0.51, 0.91)	0.73 (0.42, 0.89)	0.93 (0.59, 0.99)	0.82 (0.63, 0.92)
9 months	0.66 (0.39, 0.83)	0.64 (0.34, 0.84)	0.57 (0.28, 0.78)	0.60 (0.40, 0.76)
12 months	0.53 (0.27, 0.73)	0.56 (0.27, 0.78)	0.57 (0.28, 0.78)	0.56 (0.36, 0.72)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.56 (0.266)	0.64 (0.274)	0.64 (0.239)
95% CI [b]		0.22, 1.42	0.27, 1.48	0.31, 1.33
Two-sided p-value [c]		0.3408	0.3112	0.3265

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.9
Summary of overall survival
Intent to treat analysis set (patients with ECOG 1)

	Group 1 (GC Day 1 and 8) (N=19)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=16)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=14)	Group 2 and Group 3 (N=30)
Duration on Study (months)				
n	19	16	14	30
Mean (SD)	10.5 (7.21)	12.7 (10.40)	14.7 (8.70)	13.6 (9.54)
Median	9.7	8.3	13.0	11.1
Min, Max	0.1, 24.1	1.3, 28.1	3.9, 32.7	1.3, 32.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:28

Table 14.2.9.10
Summary of overall survival
Intent to treat analysis set (patients with 0 prior lines of therapy)

	Group 1 (GC Day 1 and 8) (N=21)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=22)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=21)	Group 2 and Group 3 (N=43)
Number of deaths, n (%)	17 (81.0%)	10 (45.5%)	12 (57.1%)	22 (51.2%)
Number of patients censored, n (%)	4 (19.0%)	12 (54.5%)	9 (42.9%)	21 (48.8%)
OS (months) (95% CI) [a]				
25%	6.3 (0.1, 12.8)	7.1 (3.1, 19.6)	8.8 (3.9, 19.4)	7.5 (4.7, 17.7)
Median	13.8 (6.3, 17.8)	20.1 (7.1, NE)	19.8 (8.8, NE)	19.8 (10.2, NE)
75%	17.8 (13.8, 18.8)	NE (20.1, NE)	32.7 (19.8, NE)	NE (32.7, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.95 (0.71, 0.99)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
6 months	0.78 (0.52, 0.91)	0.75 (0.50, 0.89)	0.95 (0.71, 0.99)	0.85 (0.70, 0.93)
9 months	0.66 (0.40, 0.83)	0.70 (0.45, 0.85)	0.74 (0.48, 0.88)	0.72 (0.55, 0.84)
12 months	0.60 (0.34, 0.79)	0.59 (0.34, 0.77)	0.74 (0.48, 0.88)	0.67 (0.49, 0.79)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.38 (0.162)	0.30 (0.125)	0.35 (0.120)
95% CI [b]		0.16, 0.87	0.14, 0.68	0.18, 0.69
Two-sided p-value [c]		0.0233	0.0048	0.0025

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.10
Summary of overall survival
Intent to treat analysis set (patients with 0 prior lines of therapy)

	Group 1 (GC Day 1 and 8) (N=21)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=22)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=21)	Group 2 and Group 3 (N=43)
Duration on Study (months)				
n	21	22	21	43
Mean (SD)	10.3 (7.45)	15.7 (11.35)	17.6 (9.83)	16.6 (10.56)
Median	9.9	13.8	17.8	17.7
Min, Max	0.1, 25.0	2.3, 32.8	3.9, 33.7	2.3, 33.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.11
Summary of overall survival
Intent to treat analysis set (patients with 1-2 prior lines of therapy)

	Group 1 (GC Day 1 and 8) (N=13)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=11)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=14)	Group 2 and Group 3 (N=25)
Number of deaths, n (%)	8 (61.5%)	3 (27.3%)	8 (57.1%)	11 (44.0%)
Number of patients censored, n (%)	5 (38.5%)	8 (72.7%)	6 (42.9%)	14 (56.0%)
OS (months) (95% CI) [a]				
25%	4.2 (0.3, 9.7)	14.0 (1.3, NE)	8.7 (3.9, 13.1)	12.9 (1.3, 15.3)
Median	9.7 (2.8, NE)	NE (13.0, NE)	15.3 (6.2, NE)	15.3 (12.9, NE)
75%	12.6 (7.5, NE)	NE (14.0, NE)	NE (13.1, NE)	NE (15.3, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.82 (0.45, 0.95)	0.91 (0.51, 0.99)	1.00 (1.00, 1.00)	0.96 (0.75, 0.99)
6 months	0.64 (0.30, 0.85)	0.91 (0.51, 0.99)	0.85 (0.51, 0.96)	0.88 (0.66, 0.96)
9 months	0.55 (0.23, 0.78)	0.91 (0.51, 0.99)	0.68 (0.35, 0.87)	0.78 (0.55, 0.90)
12 months	0.33 (0.08, 0.61)	0.91 (0.51, 0.99)	0.68 (0.35, 0.87)	0.78 (0.55, 0.90)

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:30

Table 14.2.9.11
Summary of overall survival
Intent to treat analysis set (patients with 1-2 prior lines of therapy)

	Group 1 (GC Day 1 and 8) (N=13)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=11)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=14)	Group 2 and Group 3 (N=25)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.12 (0.107)	0.30 (0.183)	0.26 (0.140)
95% CI [b]		0.02, 0.68	0.09, 0.99	0.09, 0.75
Two-sided p-value [c]		0.0211	0.0360	0.0063

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:30

Table 14.2.9.11
Summary of overall survival
Intent to treat analysis set (patients with 1-2 prior lines of therapy)

	Group 1 (GC Day 1 and 8) (N=13)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=11)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=14)	Group 2 and Group 3 (N=25)
Duration on Study (months)				
n	13	11	14	25
Mean (SD)	8.6 (8.32)	17.0 (11.16)	13.4 (8.81)	15.0 (9.86)
Median	7.5	14.0	13.0	13.1
Min, Max	0.1, 25.7	1.3, 33.6	3.5, 31.9	1.3, 33.6

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:30

Table 14.2.9.12
Summary of overall survival
Intent to treat analysis set (Caucasian patients)

	Group 1 (GC Day 1 and 8) (N=28)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=22)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=28)	Group 2 and Group 3 (N=50)
Number of deaths, n (%)	20 (71.4%)	6 (27.3%)	17 (60.7%)	23 (46.0%)
Number of patients censored, n (%)	8 (28.6%)	16 (72.7%)	11 (39.3%)	27 (54.0%)
OS (months) (95% CI) [a]				
25%	5.8 (0.3, 9.9)	19.6 (3.1, NE)	8.8 (3.9, 15.6)	12.9 (5.1, 17.8)
Median	12.6 (6.3, 15.6)	NE (19.6, NE)	17.8 (12.9, 32.7)	22.3 (17.7, NE)
75%	17.8 (12.6, 18.8)	NE (NE, NE)	32.7 (19.4, NE)	NE (32.7, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.88 (0.67, 0.96)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
6 months	0.75 (0.52, 0.88)	0.86 (0.62, 0.95)	0.89 (0.70, 0.96)	0.88 (0.75, 0.94)
9 months	0.65 (0.42, 0.81)	0.81 (0.56, 0.92)	0.73 (0.52, 0.86)	0.76 (0.61, 0.86)
12 months	0.50 (0.28, 0.69)	0.81 (0.56, 0.92)	0.73 (0.52, 0.86)	0.76 (0.61, 0.86)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.16 (0.080)	0.38 (0.132)	0.28 (0.092)
95% CI [b]		0.06, 0.43	0.19, 0.75	0.15, 0.54
Two-sided p-value [c]		0.0002	0.0003	<0.0001

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.12
Summary of overall survival
Intent to treat analysis set (Caucasian patients)

	Group 1 (GC Day 1 and 8) (N=28)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=22)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=28)	Group 2 and Group 3 (N=50)
Duration on Study (months)				
n	28	22	28	50
Mean (SD)	8.8 (7.21)	18.8 (11.22)	16.4 (9.36)	17.4 (10.19)
Median	8.4	21.5	16.6	18.4
Min, Max	0.1, 25.7	2.3, 33.6	3.9, 33.7	2.3, 33.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.13
Summary of overall survival
Intent to treat analysis set (non-Caucasian patients)

	Group 1 (GC Day 1 and 8) (N=6)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=11)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=7)	Group 2 and Group 3 (N=18)
Number of deaths, n (%)	5 (83.3%)	7 (63.6%)	3 (42.9%)	10 (55.6%)
Number of patients censored, n (%)	1 (16.7%)	4 (36.4%)	4 (57.1%)	8 (44.4%)
OS (months) (95% CI) [a]				
25%	5.4 (3.8, 16.0)	4.3 (1.3, 10.2)	8.7 (6.0, NE)	8.7 (1.3, 10.2)
Median	11.8 (3.8, 25.0)	10.2 (3.4, NE)	15.3 (6.0, NE)	13.0 (6.0, NE)
75%	25.0 (5.4, 25.0)	14.0 (9.4, NE)	NE (8.7, NE)	NE (13.0, NE)
Probability of being alive (95% CI) at [a]				
3 months	1.00 (1.00, 1.00)	0.91 (0.51, 0.99)	1.00 (1.00, 1.00)	0.94 (0.67, 0.99)
6 months	0.67 (0.19, 0.90)	0.71 (0.34, 0.90)	1.00 (1.00, 1.00)	0.82 (0.54, 0.94)
9 months	0.50 (0.11, 0.80)	0.71 (0.34, 0.90)	0.63 (0.14, 0.89)	0.68 (0.39, 0.85)
12 months	0.50 (0.11, 0.80)	0.47 (0.15, 0.74)	0.63 (0.14, 0.89)	0.53 (0.25, 0.74)

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.13
Summary of overall survival
Intent to treat analysis set (non-Caucasian patients)

	Group 1 (GC Day 1 and 8) (N=6)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=11)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=7)	Group 2 and Group 3 (N=18)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.72 (0.475)	0.19 (0.182)	0.62 (0.387)
95% CI [b]		0.20, 2.62	0.03, 1.27	0.18, 2.11
Two-sided p-value [c]		0.8798	0.1531	0.4369

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.13
Summary of overall survival
Intent to treat analysis set (non-Caucasian patients)

	Group 1 (GC Day 1 and 8) (N=6)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=11)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=7)	Group 2 and Group 3 (N=18)
Duration on Study (months)				
n	6	11	7	18
Mean (SD)	13.6 (9.47)	10.7 (9.16)	14.1 (10.73)	12.0 (9.64)
Median	11.8	9.4	8.7	9.0
Min, Max	3.8, 25.0	1.3, 29.1	3.5, 31.9	1.3, 31.9

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.14
Summary of overall survival
Intent to treat analysis set (patients in the United States)

	Group 1 (GC Day 1 and 8) (N=28)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=28)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=27)	Group 2 and Group 3 (N=55)
Number of deaths, n (%)	20 (71.4%)	12 (42.9%)	16 (59.3%)	28 (50.9%)
Number of patients censored, n (%)	8 (28.6%)	16 (57.1%)	11 (40.7%)	27 (49.1%)
OS (months) (95% CI) [a]				
25%	5.4 (0.3, 8.3)	9.4 (3.1, 19.6)	8.7 (3.9, 15.3)	8.7 (4.5, 14.0)
Median	10.5 (5.8, 16.0)	20.1 (10.2, NE)	17.7 (12.9, NE)	19.6 (13.1, NE)
75%	17.8 (10.5, 25.0)	NE (NE, NE)	32.7 (19.4, NE)	NE (32.7, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.91 (0.70, 0.98)	0.96 (0.77, 0.99)	1.00 (1.00, 1.00)	0.98 (0.88, 1.00)
6 months	0.70 (0.47, 0.84)	0.81 (0.60, 0.92)	0.88 (0.68, 0.96)	0.85 (0.72, 0.92)
9 months	0.56 (0.33, 0.73)	0.77 (0.55, 0.89)	0.72 (0.51, 0.86)	0.75 (0.60, 0.84)
12 months	0.46 (0.24, 0.65)	0.68 (0.46, 0.83)	0.72 (0.51, 0.86)	0.70 (0.55, 0.81)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.31 (0.120)	0.33 (0.123)	0.35 (0.107)
95% CI [b]		0.14, 0.66	0.16, 0.69	0.19, 0.64
Two-sided p-value [c]		0.0048	0.0005	0.0002

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.14
Summary of overall survival
Intent to treat analysis set (patients in the United States)

	Group 1 (GC Day 1 and 8) (N=28)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=28)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=27)	Group 2 and Group 3 (N=55)
Duration on Study (months)				
n	28	28	27	55
Mean (SD)	8.8 (7.43)	15.9 (11.39)	16.3 (9.91)	16.1 (10.59)
Median	6.9	13.5	15.3	15.3
Min, Max	0.1, 25.0	1.3, 33.6	3.5, 33.7	1.3, 33.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.15
Summary of overall survival
Intent to treat analysis set (patients not in the United States)

	Group 1 (GC Day 1 and 8) (N=6)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=5)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=8)	Group 2 and Group 3 (N=13)
Number of deaths, n (%)	5 (83.3%)	1 (20.0%)	4 (50.0%)	5 (38.5%)
Number of patients censored, n (%)	1 (16.7%)	4 (80.0%)	4 (50.0%)	8 (61.5%)
OS (months) (95% CI) [a]				
25%	9.7 (0.1, 13.8)	NE (5.1, NE)	8.8 (7.5, 19.8)	8.8 (5.1, NE)
Median	13.2 (0.1, NE)	NE (5.1, NE)	18.8 (7.5, NE)	NE (7.5, NE)
75%	18.8 (9.7, NE)	NE (5.1, NE)	NE (8.8, NE)	NE (19.8, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.83 (0.27, 0.97)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
6 months	0.83 (0.27, 0.97)	0.80 (0.20, 0.97)	1.00 (1.00, 1.00)	0.92 (0.57, 0.99)
9 months	0.83 (0.27, 0.97)	0.80 (0.20, 0.97)	0.67 (0.19, 0.90)	0.72 (0.35, 0.90)
12 months	0.67 (0.19, 0.90)	0.80 (0.20, 0.97)	0.67 (0.19, 0.90)	0.72 (0.35, 0.90)

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:30

Table 14.2.9.15
Summary of overall survival
Intent to treat analysis set (patients not in the United States)

	Group 1 (GC Day 1 and 8) (N=6)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=5)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=8)	Group 2 and Group 3 (N=13)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.26 (0.297)	0.41 (0.327)	0.33 (0.224)
95% CI [b]		0.03, 2.46	0.09, 1.95	0.09, 1.25
Two-sided p-value [c]		0.2626	0.3395	0.1353

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:30

Table 14.2.9.15
Summary of overall survival
Intent to treat analysis set (patients not in the United States)

	Group 1 (GC Day 1 and 8) (N=6)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=5)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=8)	Group 2 and Group 3 (N=13)
Duration on Study (months)				
n	6	5	8	13
Mean (SD)	13.4 (8.64)	17.3 (10.65)	14.7 (8.59)	15.7 (9.09)
Median	13.2	22.9	13.3	17.8
Min, Max	0.1, 25.7	5.1, 26.8	5.7, 27.7	5.1, 27.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:30

Table 14.2.9.16
Summary of overall survival
Intent to treat analysis set (patients with positive BRCA classification)

	Group 1 (GC Day 1 and 8) (N=4)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=2)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=2)	Group 2 and Group 3 (N=4)
Number of deaths, n (%)	2 (50.0%)	1 (50.0%)	2 (100.0%)	3 (75.0%)
Number of patients censored, n (%)	2 (50.0%)	1 (50.0%)	0	1 (25.0%)
OS (months) (95% CI) [a]				
25%	13.9 (13.9, 18.8)	14.0 (NE, NE)	6.2 (6.2, 19.4)	6.2 (6.2, 19.4)
Median	16.4 (13.9, 18.8)	14.0 (NE, NE)	12.8 (6.2, 19.4)	14.0 (6.2, 19.4)
75%	18.8 (13.9, 18.8)	14.0 (NE, NE)	19.4 (6.2, 19.4)	19.4 (6.2, 19.4)
Probability of being alive (95% CI) at [a]				
3 months	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
6 months	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
9 months	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.50 (0.01, 0.91)	0.67 (0.05, 0.95)
12 months	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	0.50 (0.01, 0.91)	0.67 (0.05, 0.95)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	1.41 (2.030)	NE [d]	NE [d]
95% CI [b]		0.08, 23.57		
Two-sided p-value [c]		NE	0.2253	0.2253

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
[d] HR less than 0.00001 or greater than 10000 are considered Not Estimable (NE) because the small sample size and event rates make them uninterpretable.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.16
Summary of overall survival
Intent to treat analysis set (patients with positive BRCA classification)

	Group 1 (GC Day 1 and 8) (N=4)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=2)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=2)	Group 2 and Group 3 (N=4)
Duration on Study (months)				
n	4	2	2	4
Mean (SD)	8.5 (9.35)	9.7 (6.03)	12.8 (9.33)	11.3 (6.66)
Median	7.4	9.7	12.8	10.1
Min, Max	0.1, 18.8	5.5, 14.0	6.2, 19.4	5.5, 19.4

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
[d] HR less than 0.00001 or greater than 10000 are considered Not Estimable (NE) because the small sample size and event rates make them uninterpretable.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.17
Summary of overall survival
Intent to treat analysis set (patients with unknown BRCA classification)

	Group 1 (GC Day 1 and 8) (N=21)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=21)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=24)	Group 2 and Group 3 (N=45)
Number of deaths, n (%)	16 (76.2%)	8 (38.1%)	13 (54.2%)	21 (46.7%)
Number of patients censored, n (%)	5 (23.8%)	13 (61.9%)	11 (45.8%)	24 (53.3%)
OS (months) (95% CI) [a]				
25%	8.3 (0.1, 12.6)	7.1 (3.1, 20.1)	8.8 (3.9, 15.3)	8.8 (4.7, 15.3)
Median	12.8 (8.3, 17.8)	NE (7.1, NE)	15.6 (8.8, NE)	20.1 (12.9, NE)
75%	18.5 (12.8, NE)	NE (NE, NE)	32.7 (19.8, NE)	NE (32.7, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.85 (0.60, 0.95)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
6 months	0.79 (0.54, 0.92)	0.79 (0.54, 0.92)	0.91 (0.69, 0.98)	0.86 (0.71, 0.93)
9 months	0.74 (0.48, 0.88)	0.74 (0.48, 0.88)	0.71 (0.46, 0.86)	0.73 (0.56, 0.84)
12 months	0.57 (0.32, 0.76)	0.68 (0.42, 0.84)	0.71 (0.46, 0.86)	0.70 (0.53, 0.82)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.30 (0.137)	0.47 (0.185)	0.39 (0.134)
95% CI [b]		0.12, 0.73	0.22, 1.02	0.20, 0.76
Two-sided p-value [c]		0.0127	0.0402	0.0058

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.17
Summary of overall survival
Intent to treat analysis set (patients with unknown BRCA classification)

	Group 1 (GC Day 1 and 8) (N=21)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=21)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=24)	Group 2 and Group 3 (N=45)
Duration on Study (months)				
n	21	21	24	45
Mean (SD)	11.2 (8.40)	17.1 (11.47)	14.9 (9.62)	15.9 (10.46)
Median	10.5	19.6	14.1	15.3
Min, Max	0.1, 25.7	2.3, 32.8	3.5, 33.7	2.3, 33.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.18
Summary of overall survival
Intent to treat analysis set (patients histological classification TNBC)

	Group 1 (GC Day 1 and 8) (N=25)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=24)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=22)	Group 2 and Group 3 (N=46)
Number of deaths, n (%)	18 (72.0%)	10 (41.7%)	11 (50.0%)	21 (45.7%)
Number of patients censored, n (%)	7 (28.0%)	14 (58.3%)	11 (50.0%)	25 (54.3%)
OS (months) (95% CI) [a]				
25%	6.3 (0.1, 10.5)	10.2 (1.3, 19.6)	12.9 (3.9, 17.8)	12.9 (6.2, 17.7)
Median	12.6 (6.3, 16.0)	20.1 (10.2, NE)	19.8 (12.9, NE)	20.1 (14.0, NE)
75%	17.8 (12.8, NE)	NE (NE, NE)	32.7 (19.8, NE)	NE (32.7, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.92 (0.70, 0.98)	0.96 (0.74, 0.99)	1.00 (1.00, 1.00)	0.98 (0.86, 1.00)
6 months	0.78 (0.55, 0.90)	0.83 (0.61, 0.93)	0.95 (0.71, 0.99)	0.89 (0.75, 0.95)
9 months	0.63 (0.40, 0.80)	0.78 (0.54, 0.90)	0.80 (0.55, 0.92)	0.79 (0.63, 0.88)
12 months	0.53 (0.30, 0.71)	0.72 (0.48, 0.87)	0.80 (0.55, 0.92)	0.76 (0.60, 0.86)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.38 (0.154)	0.35 (0.143)	0.37 (0.124)
95% CI [b]		0.17, 0.84	0.16, 0.78	0.19, 0.71
Two-sided p-value [c]		0.0125	0.0036	0.0013

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.18
Summary of overall survival
Intent to treat analysis set (patients histological classification TNBC)

	Group 1 (GC Day 1 and 8) (N=25)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=24)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=22)	Group 2 and Group 3 (N=46)
Duration on Study (months)				
n	25	24	22	46
Mean (SD)	9.8 (7.47)	15.1 (10.50)	17.7 (9.97)	16.3 (10.22)
Median	8.4	13.5	17.7	16.3
Min, Max	0.1, 25.7	1.3, 32.8	3.5, 33.7	1.3, 33.7

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.19
Summary of overall survival
Intent to treat analysis set (patients histological classification acquired TNBC)

	Group 1 (GC Day 1 and 8) (N=7)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=7)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=11)	Group 2 and Group 3 (N=18)
Number of deaths, n (%)	5 (71.4%)	3 (42.9%)	8 (72.7%)	11 (61.1%)
Number of patients censored, n (%)	2 (28.6%)	4 (57.1%)	3 (27.3%)	7 (38.9%)
OS (months) (95% CI) [a]				
25%	4.8 (2.8, 9.9)	5.1 (4.7, NE)	6.0 (3.9, 15.3)	6.0 (3.9, 9.4)
Median	5.4 (2.8, 25.0)	NE (4.7, NE)	15.3 (4.5, 22.3)	15.3 (5.1, NE)
75%	9.9 (2.8, 25.0)	NE (5.1, NE)	22.3 (8.7, NE)	NE (15.3, NE)
Probability of being alive (95% CI) at [a]				
3 months	0.80 (0.20, 0.97)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)	1.00 (1.00, 1.00)
6 months	0.40 (0.05, 0.75)	0.67 (0.19, 0.90)	0.82 (0.45, 0.95)	0.76 (0.49, 0.90)
9 months	0.40 (0.05, 0.75)	0.67 (0.19, 0.90)	0.52 (0.20, 0.77)	0.58 (0.31, 0.77)
12 months	0.20 (0.01, 0.58)	0.50 (0.11, 0.80)	0.52 (0.20, 0.77)	0.51 (0.26, 0.72)
Comparison (Treatment Group vs Group 1)				
Adjusted HR (SE) [b]	NA	0.26 (0.242)	0.27 (0.194)	0.34 (0.206)
95% CI [b]		0.04, 1.61	0.07, 1.10	0.10, 1.12
Two-sided p-value [c]		0.3459	0.1105	0.1048

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

Table 14.2.9.19
Summary of overall survival
Intent to treat analysis set (patients histological classification acquired TNBC)

	Group 1 (GC Day 1 and 8) (N=7)	Group 2 (GC + Trilaciclib Day 1 and 8) (N=7)	Group 3 (GC + Trilaciclib Day 1/2 and 8/9) (N=11)	Group 2 and Group 3 (N=18)
Duration on Study (months)				
n	7	7	11	18
Mean (SD)	6.9 (8.70)	16.1 (13.69)	13.3 (8.80)	14.4 (10.66)
Median	4.8	9.4	8.7	9.0
Min, Max	0.1, 25.0	2.5, 33.6	3.9, 28.4	2.5, 33.6

[a] Calculated using the Kaplan-Meier method.
[b] The HR and its 95% CI are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
[c] P-value is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
Note: Unless otherwise specified, percentages are based on the number of patients in each treatment group.
CI = confidence interval; HR = hazard ratio; OS = overall survival; SE = standard error
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Tables\t_km.sas, Date/time of run: 11SEP2020:17:29

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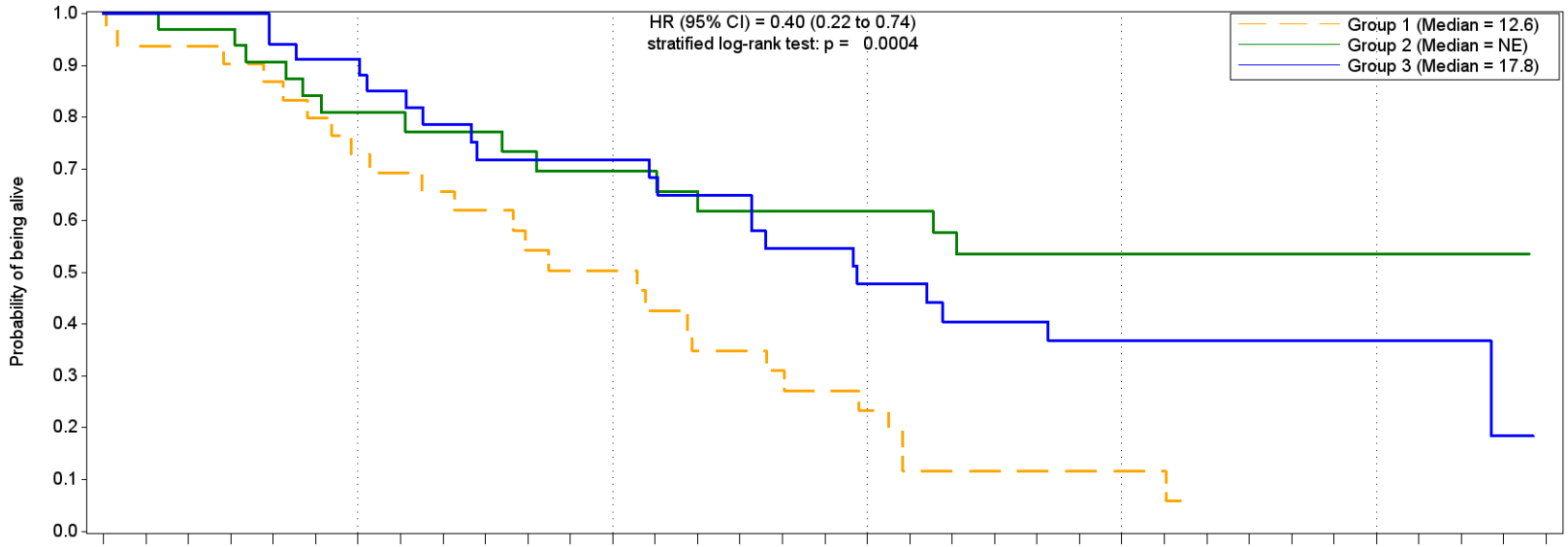
Figure 14.2.9.2
Overall survival - Kaplan-Meier curve
Intent to treat analysis set

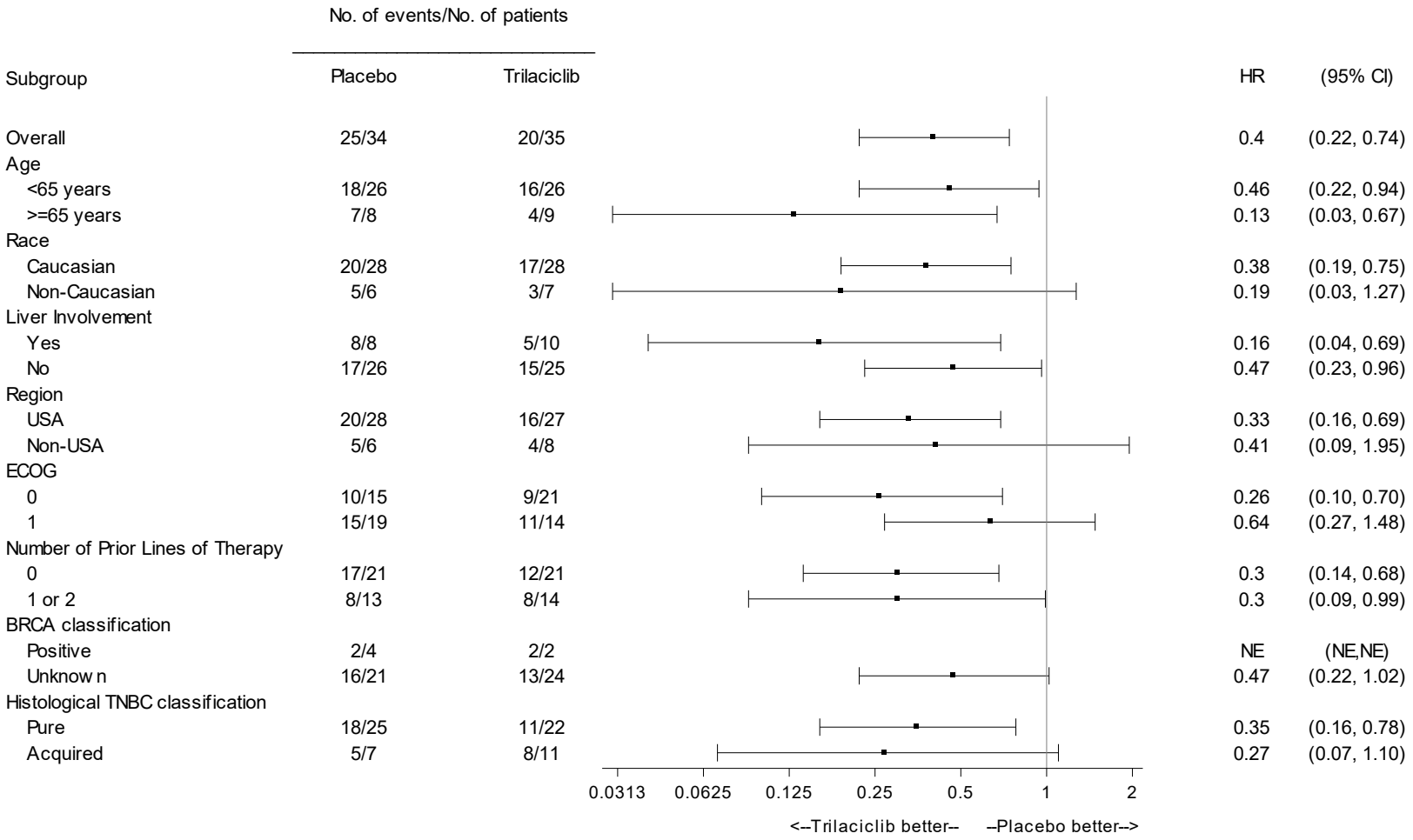


Number of patients at risk

Group 1	34	27	27	26	25	23	21 (0.73)	19	18	16	14	13	13 (0.50)	11	9	9	8	7	6	3	3	3	3	3	3	2	0	0	0	0	0	0	0	0	0
Group 2	33	33	32	31	28	26	24 (0.81)	22	20	20	19	18	18 (0.69)	18	16	16	16	16	15	15	14	13	13	12	12	12	10	8	8	5	3	3	2	1	0
Group 3	35	35	35	35	32	31	30 (0.91)	26	23	21	21	21	21 (0.72)	20	19	19	16	16	14	13	11	11	11	9	8	8	7	7	4	3	3	3	2	1	0

Note: The HR and its 95% CI comparing groups 1 and 3 are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
Note: P-value comparing groups 1 and 3 is calculated using the stratified log-rank test to account for the number of prior lines of therapy (0 versus 1 - 2) and liver involvement as the stratification factors.
CI = confidence interval; HR = hazard ratio; OS = overall survival
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Figures\f_km.sas, Date/time of run: 11SEP2020:17:35

Figure 14.2.9.3
Overall survival hazard ratio - forest plot (Group 3 Versus Group 1)
Intent to treat analysis set



Note: The HR and its 95% CI comparing groups 3 and 1 are calculated using the Cox regression model with treatment and stratification factors of number of prior lines of therapy (0 versus 1 - 2) and liver involvement.
CI = confidence interval; HR = hazard ratio.

Program: Box\Biostatistics\G1T28 Internal Analysis\Analysis\G1T28-04\OS Forest plot\OSForestPlot Run Datetime: 15OCT2020 12:23

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Listing 14.3.2.1.I
Serious Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]			Other [c]	Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA			
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Renal and urinary disorders Haematuria HEMATURIA (48)	16AUG2019 (607)	20AUG2019 (611)	Yes/3	1	2	2	7	5	5	5: CONCOMITANT MEDICATION AND CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED	Yes/ No
	Renal and urinary disorders Urinary tract obstruction URINARY TRACT OBSTRUCTION (49)	26AUG2019 (617)	31AUG2019 (622)	Yes/3	1	2	2	7	7	7	2	RECOVERED/ RESOLVED	Yes/ No
	Respiratory, thoracic and mediastinal disorders Pleural effusion PLEURAL EFFUSION (52)	04SEP2019 (626)	10SEP2019 (632)	Yes/3	1	3	3	7	7	7	2	RECOVERED/ RESOLVED	Yes/ No

[a] 1 = UNRELATED; 2 = UNLIKELY RELATED; 3 = POSSIBLY RELATED; 4 = PROBABLY RELATED; 5 = DEFINITELY RELATED.
[b] 1 = DOSE NOT CHANGED; 2 = DOSE REDUCED; 3 = DRUG INTERRUPTED; 4 = PERMANENT DISCONTINUATION; 5 = DOSE SKIPPED; 6 = DOSE DELAYED; 7 = NOT APPLICABLE; 8 = UNKNOWN.
[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.1.1.I
Patient Disposition - End of Treatment
All enrolled patients (incremental data after 28JUN2019)

Subject Number	Reason for Trilaciclib Discontinuation	Reason for Carboplatin Discontinuation	Reason for Gemcitabine Discontinuation	Date of First/Last Dose
Treatment: Trilaciclib D1D8 + GC Therapy D1D8				
1111003	Adverse Event: 94 ACUTE KIDNEY INJURY*	Adverse Event: Hematologic Toxicity: 32 PLATELET COUNT DECREASED	Adverse Event: 49 ACUTE KIDNEY INJURY	18DEC2017/ 12AUG2019
1122001	Progressive Disease*	Progressive Disease	Progressive Disease	04OCT2017/ 28AUG2019

Note: * indicates the primary reason for discontinuation of study drug.
For pt 1111003 reason for gemcitabine discontinuation should be 94 Acute Kidney Injury instead of 49.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_disp1_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.1.2.I
Patient Disposition - End of Study
All enrolled patients (incremental data after 28JUN2019)

Subject Number	Reason for Study Discontinuation	Date of Study Discontinuation	Date of Death	Reason for Death	Autopsy Performed?	Date of Last Contact
Treatment: GC Therapy D1D8						
1112007	Death	03SEP2019	03SEP2019	Disease Progression		04SEP2019
1123005	Death	16OCT2019	16OCT2019	Disease Progression		16OCT2019
1131013	Death	27AUG2019	27AUG2019	Disease Progression		27AUG2019
1131015	Study Terminated By Sponsor	25FEB2020				25FEB2020
1156001	Study Terminated By Sponsor	03FEB2020				03FEB2020
1163006	Death	03DEC2019	14OCT2019	cardiopulmonary failure		03DEC2019
Treatment: Trilaciclib D1D8 + GC Therapy D1D8						
1111003	Study Terminated By Sponsor	11FEB2020				11FEB2020
1113001	Study Terminated By Sponsor	18FEB2020				18FEB2020
1121001	Study Terminated By Sponsor	18FEB2020				18FEB2020
1122001	Study Terminated By Sponsor	20FEB2020				20FEB2020
1125008	Death	07JUL2019	07JUL2019	Disease Progression		07JUL2019
1127001	Study Terminated By Sponsor	26FEB2020				26FEB2020
1129005	Study Terminated By Sponsor	27FEB2020				27FEB2020
1131011	Study Terminated By Sponsor	25FEB2020				25FEB2020
1131014	Death	12OCT2019	12OCT2019	Disease Progression		12OCT2019
1133002	Study Terminated By Sponsor	12FEB2020				12FEB2020
1141001	Study Terminated By Sponsor	10FEB2020				10FEB2020

Listing 16.2.1.2.I
Patient Disposition - End of Study
All enrolled patients (incremental data after 28JUN2019)

Subject Number	Reason for Study Discontinuation	Date of Study Discontinuation	Date of Death	Reason for Death	Autopsy Performed?	Date of Last Contact
Treatment: Trilaciclib D1D8 + GC Therapy D1D8						
1163001	Study Terminated By Sponsor	28JAN2020				28JAN2020
1163005	Study Terminated By Sponsor	23JAN2020				23JAN2020
1165001	Study Terminated By Sponsor	12FEB2020				12FEB2020
1166001	Study Terminated By Sponsor	24JAN2020				24JAN2020
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9						
1111004	Death	06JUL2019	06JUL2019	Disease Progression		06JUL2019
1112001	Death	11OCT2019	11OCT2019	Disease Progression		11OCT2019
1113005	Study Terminated By Sponsor	05FEB2020				05FEB2020
1116001	Study Terminated By Sponsor	13FEB2020				13FEB2020
1117006	Death	18NOV2019	18NOV2019	Disease Progression		18NOV2019
1118002	Study Terminated By Sponsor	20FEB2020				20FEB2020
1122002	Study Terminated By Sponsor	13FEB2020				13FEB2020
1126002	Study Terminated By Sponsor	21FEB2020				21FEB2020
1128002	Death	08JAN2020	08JAN2020	Disease Progression		21FEB2020
1130001	Study Terminated By Sponsor	28FEB2020				28FEB2020
1145003	Study Terminated By Sponsor	06FEB2020				06FEB2020
1148001	Study Terminated By Sponsor	24JAN2020				24JAN2020

Listing 16.2.1.2.I
Patient Disposition - End of Study
All enrolled patients (incremental data after 28JUN2019)

Subject Number	Reason for Study Discontinuation	Date of Study Discontinuation	Date of Death	Reason for Death	Autopsy Performed?	Date of Last Contact
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9						
1156004	Study Terminated By Sponsor	17JAN2020				17JAN2020
1164001	Death	04OCT2019	04OCT2019	Disease Progression		29OCT2019

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Screen Failure				
1017001				
1110001				
1110002				
1111006				
1113002				
1114004				
1116002				
1118004				
1120003				
1121003				
1123002				
1123003				
1124001				
1125004				
1126001				
1127002				
1129002				
1129003				
1129004				
1130002				
1131002				
1131003				
1131007				
1131008				
1131009				
1131012				
1133003				

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Screen Failure				
1139001				
1145006				
1148002				
1154001				
1154003				
1155002				
1156006				
1162001				
1163003				
1163004				
1163007				
1165002				
1171001				
Treatment: GC Therapy D1D8				
1017002	30MAR2018 (149)	Visit/Procedure Required	Cycle 5 Day 8 Post infusions respiratory rate not taken on 08FEB2018.	Non-Key
	30MAR2018 (149)	Visit/Procedure Required	Cycle 6 Day 1 Post infusions respiratory rate not taken on 22FEB2018.	Non-Key
	12JUN2018 (223)	Informed Consent	Per WIRB Approval 04-Apr-2018, the site was required to notify all active trial subjects of the change to the 24-hour contact phone number. However, the site failed to notify subject 1017-002 prior tostudy discontinuation on 12-Apr-2018. Subject was notified during PTV2 on 11June2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1017002	12JUN2018 (223)	Visit Schedule	Post-Treatment Visit 1 (12-Apr-2018) FLOW immunological sample was collected and submitted out of window on 26-Apr-2018.	Non-Key
	12JUN2018 (223)	Visit Schedule	Post-Treatment Visit 1 (12-Apr-2018) PBMC immunological sample was collected and submitted out of window on 26-Apr-2018.	Non-Key
	19AUG2018 (291)	Concomitant Medications	Pegfilgrastim was administered on C5D8 (08Feb2018) and on C6D8 (01Mar2018) Per protocol Pegfilgrastim should only be give 24-48 hours after D8/9.	Key
	19AUG2018 (291)	Concomitant Medications	Subject was given G-CSF on 17Jan2018 (Filgrastim) and 18Jan2018 (Pegfilgrastim). Subject received Group 1 study treatment (Gem/Carbo) on 18Jan2018. Filgrastim should not have been administered lessthan 24 hours prior to the Gem/Carbo. Pegfilgrastim can only be administered 24 to 48 hours after D8/9	Key
1110003				
1111005	07APR2018 (74)	Visit/Procedure Required	Subject 1111-005 Screening 12-Lead ECG RR interval was not assessed on 17Jan2018.	Non-Key
	29JUL2018 (187)	Visit Schedule	C6D8 on 16May2018 was conducted 1 day early. The visit should have been done on 17May2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1111005	14AUG2018 (203)	Enrollment Criteria	Patient was randomized under the wrong prior lines of systemic therapy stratification factor. Per protocol, any therapy given in the adjuvant setting where the patient progresses in < 12 months aftercompletion of therapy is considered a prior line of therapy. The patient ended adjuvant radiotherapy on 9Jan17 and recurred on 22Nov17 which is less than 12 months and should have been considered 1prior line f therapy.	Non-Key
	19OCT2018 (269)	Laboratory	Cycle 10 Day 15 Safety Lab not completed on 15AUG2018.	Non-Key
	04APR2019 (436)	Visit/Procedure Required	Immunologic Markers in Blood (flow and PBMC) samples note collected for Subject 1111-005 Post-Treatment Visit 2 (+60 days). Per DC Beverly Dunning, a lab kit was collected on this day but was for adifferent study.	Non-Key
1112007	14DEC2018 (291)	Visit/Procedure Required	Post Treatment Visit +60-days (16-Aug-2018) PBMC and FLOW lab samples were not collected.	Non-Key
	14DEC2018 (291)	Visit/Procedure Required	Post Treatment Visit 1 (12-Jun-2018) FACT An & B questionnaires were not completed.	Non-Key
	14DEC2018 (291)	Visit/Procedure Required	Post-Treatment Visit 1 (12-Jun-2018) PBMC and FLOW lab samples were not collected.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1113003	26OCT2017 (28)	Visit/Procedure Required	Patient 1113-003 Cycle 1 Day 8 vital assessments were not recorded for post-Gemcitabine/pre-Carboplatin and post-Carboplatin infusions.	Non-Key
	15JAN2018 (109)	Non-compliance	Cycle 3 Day 1 (04Dec2017) and Day 8 (11Dec2017) visits conducted when Patient 1118-003 should have been discontinued from study participation on 27Nov2017. The start of Cycle 3 was delayed 5 weeks dueto hematological toxicity, which exceeds the protocol maximum delay of 4 weeks without medical monitor approval.	Key
	03APR2018 (187)	Laboratory	Eosinophils were not done with the hematology labs for C2D8 on 30-Oct-2017.	Non-Key
	03APR2018 (187)	Laboratory	Hematology Labs for C2D36 (24-Nov-2017) were not done.	Non-Key
	27APR2018 (211)	Visit Schedule	Visit C2D1 Occurred 3 days out of window. Visit should have occurred on 20-Oct-2017 but was not completed until 23-Oct-2017	Non-Key
	26JUN2018 (271)	Visit/Procedure Required	The subject's vital signs were not collected at C3D8 on 11December2017	Non-Key
	29JUN2018 (274)	Laboratory	Urine protein was not assessed at the screening visit on 18Sept2017.	Non-Key
	05JUL2018 (280)	Laboratory	Microscopic Urinalysis was not performed during the Screening visit (18Sep2017).	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1113003	14MAY2019 (593)	Dosing	Multiple dose modifications made at the one visit - Both Carboplatin and Gemcitabine were reduced at C3D1 (4 Dec 2017)	Non-Key
1114001				
1114002	31JAN2018 (163)	Visit/Procedure Required	Subject 1114002 Cycle 6 Day1, 05Dec2017, Infusion vitals not done correctly (Only vitals post-carboplatin was taken).	Non-Key
	12JUN2018 (295)	Dosing	The C1D1 carboplatin infusion on 22Aug2017 was 33 minutes. This was 3 minutes longer than the protocol required 30 minutes.	Non-Key
	12JUN2018 (295)	Visit/Procedure Required	Predose Carboplatin and Predose Gemcitabine vital signs were not collected C3D1.	Non-Key
	12JUN2018 (295)	Visit/Procedure Required	Predose Carboplatin vital signs were not taken at C1D1, (8/22/2017) C1D8, (08/29/2017) C2D8, (09/19/2017) C4D8, (10/31/2017) C5D1, (11/14/2017) C7D1 (12/26/2017).	Non-Key
	12JUN2018 (295)	Visit/Procedure Required	Respiration rate and temperature were not collected at C2D1 on 12Sept2017.	Non-Key
	26JUN2018 (309)	Visit/Procedure Required	Vital signs for C4D1 on 24Oct2017 were not collected.	Non-Key
	03SEP2018 (378)	Concomitant Medications	The subject had a grade 3 Neutropenia on 10-Oct-2018 on C3D8. The subject should have started GCSF during the next cycle. The site did not use GCSF for this subject during their study treatment.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1114002	16SEP2018 (391)	Dosing	The subject's ANC was 0.9X10^9 which is less than the required 1.0X10^9 criteria for dosing at C2D8 on 19Sept2017.	Key
	10MAY2019 (627)	Dosing	C6D1 (5 Dec 17)dose of Gem is 1000 however C3D8(10 Oct 17) and C5D8 (21 Nov 17)were skipped due to Neutropnia #9 and 12, therefore according to protocol Gem dose should have been reduced to 800.	Non-Key
1114003	18APR2018 (160)	Laboratory	The Hematology labs for C2D15 on 15-Dec-2017 were not done	Non-Key
	09MAY2018 (181)	Visit/Procedure Required	PTV #1 was not completed. PTV #1 should have been done on or about 22Dec2017.	Non-Key
	29JUN2018 (232)	Visit Schedule	Screening CT was done 4 days out of window. The CT was done on 06Oct2017 but the first dose was on 10Nov2017.	Non-Key
	05JUL2018 (238)	Visit Schedule	C1D15 was conducted two days out of window on 22Nov2018. The visit was due on 24Nov2017	Non-Key
	29JUL2018 (262)	Visit Schedule	The site was unable to contact the patient for the safety follow-up phone call 30 days after last dose of IP. This call would have been expected on 15-Jan-2018.	Non-Key
	29JUL2018 (262)	Visit/Procedure Required	Pre-dose vitals were not collected for C1D8 on 17Nov2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1114005	28JUN2018 (99)	Dosing	Subject 1114005 met criteria for dosing at C3D8 on 22May2018, but dose was skipped because the coordinator had initially incorrectly identified the visit as C3D15 instead of C3D8.	Non-Key
	28JUN2018 (99)	Visit Schedule	The C3D1 visit was conducted 3 days out of window. Visit should have occurred on 10May2018 but was done on 14May2018.	Non-Key
	12SEP2018 (175)	Enrollment Criteria	Subject's bilirubin was 1.8mg/dL which was more than 1.5X the ULN of normal at screening on 02Mar2018. The subject's bilirubin was 1.7mg/dL at C1D1 which is > than 1.5X ULN. This is violation ofinclusion criteria #9 for Protocol version 4 Amendment 3.	Key
	28SEP2018 (191)	Dosing	On 12May2018, C2D1, there should have been a dose reduction but the site did not reduce either chemotherapeutic agent.	Non-Key
	28SEP2018 (191)	Dosing	The site did not stop one of the chemotherapeutic agents after multiple heme toxicities at C4D1 on 30May2018.	Non-Key
	13MAY2019 (418)	Visit/Procedure Required	Post Treatment Visit +60 (09-Aug-2018) was not conducted.	Non-Key
1116004	21MAY2018 (110)	Visit/Procedure Required	Post-Treatment Visit 2 (+60 days) immunological flow and PBMC marker not collected on 01MAY2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1117001	05FEB2018 (28)	Visit/Procedure Required	Cycle 1 Day 1 (09Jan2018) PBMC lab sample was not collected.	Non-Key
	09MAR2018 (60)	Visit/Procedure Required	Cycle 1 Day 1 (09Jan2018) post-Carboplatin infusion vital sign assessment was not completed.	Non-Key
	09MAR2018 (60)	Visit/Procedure Required	Cycle 2 Day 1 (30Jan2018) post-Carboplatin infusion vital sign assessment was not completed.	Non-Key
	09MAR2018 (60)	Visit/Procedure Required	Cycle 2 Day 1 (30Jan2018) post-Gemcitabine/pre-Carboplatin infusion vital sign assessment was not completed.	Non-Key
	09MAR2018 (60)	Visit/Procedure Required	Cycle 2 Day 8 (16Jan2018) post-Gemcitabine/pre-Carboplatin infusion vital sign assessment taken during the Carboplatin infusion.	Non-Key
	29MAR2018 (80)	Visit/Procedure Required	C2D8 Post Dose Carboplatin/ Predose Gemcitabine vitals were not collected.	Non-Key
	29MAR2018 (80)	Visit/Procedure Required	Cycle 4 day 1(13Mar18) post dose vitals were not collected after infusion.	Non-Key
	29MAR2018 (80)	Visit/Procedure Required	Cycle 4 day 8 (20Mar18) Predose Carboplatin Respiratory rate was inadvertently not assessed.	Non-Key
	29MAR2018 (80)	Visit/Procedure Required	Cycle 4 day 8(20Mar18) post dose vitals were not collected after infusion.	Non-Key
	07SEP2018 (242)	Visit/Procedure Required	Cycle 7 Day 1 (15-May-2018) respiratory rate was not assessed during the pre-Gemcitabine infusion vitals.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1117001	07SEP2018 (242)	Visit/Procedure Required	Cycle 8 Day 8 (19-Jun-2018) respiratory rate was not assessed during the post-Gemcitabine and post-Carboplatin infusion vitals.	Non-Key
	17DEC2018 (343)	Laboratory	Post Treatment Visit 1 (31-Jul-2018) Phosphorus and LDH were not completed with the Complete Metabolic Panel.	Non-Key
	17DEC2018 (343)	Visit/Procedure Required	Post Treatment Visit +60-days (25-Sep-2018) PBMC and FLOW laboratory samples were not collected.	Non-Key
	15JAN2019 (372)	Visit/Procedure Required	PTV (31 July 18) PBMC and Flow samples were not collected.	Non-Key
1117005	20JUN2018 (120)	Visit Schedule	Post-Treatment Visit 1 projected for 09-16May2018 completed out-of-window on 02May2018.	Non-Key
	20JUN2018 (120)	Visit Schedule	Safety Follow-up Call/Visit projected for 18-21May2018 conducted out-of-window on 17May2018.	Non-Key
1121002				
1123001				
1123004	04OCT2017 (30)	Dosing	Carboplatin was infused for 1 hour instead of 30 minutes on Cycle 1 Day 1 (05Sept2017) and Cycle 1 Day 8 (12Sept2017)	Non-Key
	25OCT2017 (51)	Concomitant Medications	The patient received G-CSF at Cycle 1 Day 29 on 03Oct2017.	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1123004	01MAY2018 (239)	Visit/Procedure Required	The lab tech at the site neglected to draw the immunological (PBMC) marker at PTV (26 Oct 17). The SC will ensure that all lab tubes required for study are sent to the lab prior to the pt. visit.	Non-Key
	19JUN2019 (653)	Dosing	Subject 1123004 was randomized >4 days within C1D1 visit. The subject was randomized on 30AUG2017 and the C1D1 visit on 05SEP2017.	Non-Key
	19JUN2019 (653)	Visit/Procedure Required	C1D8 (Post-dose Carboplatin/Pre-dose Gemcitabine and Post-dose Gemcitabine) vitals not taken on 12SEP2017.	Non-Key
	09AUG2019 (704)	Laboratory	Clinical Chemistry for 'Inorganic Phosphorus' and/or 'LDH' not done on C2D1 on 05Oct2017.	Non-Key
	09AUG2019 (704)	Laboratory	Clinical Chemistry for 'LDH' not done at PTV1 on 26OCT2017.	Non-Key
	09AUG2019 (704)	Laboratory	Clinical chemistry for 'Inorganic Phosphorus' and/or 'LDH' not done on C1D1 on 05Sep2017.	Non-Key
	09AUG2019 (704)	Laboratory	Clinical chemistry for 'Inorganic Phosphorus' and/or 'LDH' not done on C1D29 on 03Oct2017.	Non-Key
1123005	25OCT2017 (27)	Concomitant Medications	The patient received G-CSF in Cycle 1 Day 8 (10Oct2017) which is against the protocol.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1123005	25OCT2017 (27)	Dosing	At the C2D1 (20Oct2017) visit, Carboplatin infusion was infused over 1 hour by the infusion nurse. This occurred under protocol amendment 2.	Non-Key
	17JAN2018 (111)	Visit Schedule	The pt. did not have a PE done C4D1, 08Dec2017 . The PE was completed 3 days after the visit. The MD was out of the office the day of the visit. The Pt. was seen following the visit date.	Non-Key
	28MAR2018 (181)	Visit Schedule	C5D1 (29-Dec-2017) PBMC and Immunologic marker samples were collected on 03-Jan-2018 which is 5 days out of window.	Non-Key
	03MAY2018 (217)	Laboratory	The site did not collect C8D15 (19Mar2018) hematology labs.	Non-Key
	03MAY2018 (217)	Visit/Procedure Required	The FACT-A and FACT-B questionnaire was not completed at the C8D1 visit on 05Mar2018.	Non-Key
	03MAY2018 (217)	Visit/Procedure Required	The site did not conduct a physical exam at C9D1 (09Apr2018).	Non-Key
	12JUN2018 (257)	Visit/Procedure Required	The site staff did not complete temperature collection at post treatment visit 1 dated 10 May 2018.	Non-Key
	23AUG2018 (329)	Laboratory	The site staff neglected to add Inorganic phosphorus to chemistry lab test for cycle 8 day 22 on 26 Mar 2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1123005	29AUG2018 (335)	Dosing	On 15/Dec/2017-Should have been Day 15- but instead the pt was treated again with chemotherapy per the sites treating guidelines.	Key
	06SEP2018 (343)	Visit/Procedure Required	The site did not draw the Immunologic Markers in Blood at the PTV # 2 on 03 Jul 2018.	Non-Key
	08MAY2019 (587)	Visit Schedule	C3D1(14 Nov 2017) was conducted 4 days out of window.	Non-Key
	08MAY2019 (587)	Visit Schedule	Immunologic Markers for C3D1 (14 Nov 17) were collected 4 days out of window.	Non-Key
	15MAY2019 (594)	Concomitant Medications	G-CSF not administered at C6,C8 & C9. (2 Feb, 5 March & 9 April 2018)	Non-Key
	15MAY2019 (594)	Dosing	C2D22(10Nov17) Gemcitabine was not reduced after 2nd episode of low ANC at cycle 3. Subject has 3rd episode of low ANC (C3D8 21 Nov 17). Carboplatin and Gemcitabine was reduced at same cycle.	Non-Key
	15MAY2019 (594)	Dosing	Fourth episode of Low ANC at C4 D22 (0.37) and one chemo agent should have been dropped at Cycle 5. This didn't happen. Additionally, subsequent Low ANCs occurred at C5D22 (0.95) (5th episode); C6 D8(0.6); C7 D8 (0.6); and a Low Platelet at C8 D22 (94); however, no action taken with drug following these low Hem values. Drug eventually discontinued after Cycle 9	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1123005	15MAY2019 (594)	Laboratory	Clinical Chemistry for 'LDH' not done at C6D1 (2 Feb 2018)	Non-Key
	15MAY2019 (594)	Laboratory	Phosphorus and LDH not done on C1D1 C2D1, C4D1, C8D1 and PTV1 (29 Sep, 20 Oct, 1 Dec, 2017 & 5 Mar, 10 May 2018)	Non-Key
	15MAY2019 (594)	Visit Schedule	C4D8 (8 Dec 2017) Hematology Labs collected greater than 24 hours prior to chemotherapy.	Key
	15MAY2019 (594)	Visit/Procedure Required	C1D1 (29 sep 17) flow sample not collected.	Non-Key
	15MAY2019 (594)	Visit/Procedure Required	C7D1(16 Feb 2018) Post-dose Carboplatin/Pre-dose Gemcitabine and Post-dose Gemcitabine vitals signs not done.	Non-Key
	15MAY2019 (594)	Visit/Procedure Required	C8D1 (5Mar18) Post-dose Carboplatin/Pre-dose Gemcitabine and Post-dose Gemcitabine vital signs not obtained.	Non-Key
	15MAY2019 (594)	Visit/Procedure Required	C8D8 (12Mar18)Post-dose Carboplatin/Pre-dose Gemcitabine and Post-dose Gemcitabine vital signs not obtained.	Non-Key
	15MAY2019 (594)	Visit/Procedure Required	C9D8 (16Apr18)Post-dose Carboplatin/Pre-dose Gemcitabine and Post-dose Gemcitabine vital signs not obtained.	Non-Key
	19JUN2019 (629)	Laboratory	Cycle 2 Day 15 hematology labs missed on 08NOV2017.	Non-Key
	19JUN2019 (629)	Visit/Procedure Required	C4D8 vitals not taken in between infusions on 08DEC2017.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1123005	09AUG2019 (680)	Concomitant Medications	Subject 1123005 received G-CSF on 13NOV2017 prior to chemotherapy on 14NOV2017 (C3D1 visit).	Key
	09AUG2019 (680)	Laboratory	Clinical Chemistry for 'Inorganic Phosphorus' and/or 'LDH' not done on C2D22 on 10NOV2017.	Non-Key
	09AUG2019 (680)	Laboratory	Clinical Chemistry for 'Inorganic Phosphorus' and/or 'LDH' not done on C5D22 on 21DEC2017.	Non-Key
	09AUG2019 (680)	Laboratory	Clinical Chemistry for 'Inorganic Phosphorus' and/or 'LDH' not done on C8D22 on 26MAR2018.	Non-Key
	09AUG2019 (680)	Laboratory	Clinical Chemistry for 'Inorganic Phosphorus' and/or 'LDH' not done on C9D22 on 30APR2018.	Non-Key
	09AUG2019 (680)	Visit Schedule	Hematology was obtained >24 hours prior to Gemcitabine Carboplatin (GC) dosing for subject 1123005 at visit C7D1. Hematology for this visit was collected at 1:50 PM on 15FEB2018 and the Start time ofGemcitabine Carboplatin (GC) dosing was at 2:10 PM on 16FEB2018.	Non-Key
1125006	03MAY2018 (79)	Visit/Procedure Required	The infusion site staff did not complete the VS at cycle Post dose Carboplatin/ Pre-dose Gemcitabine.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1125006	03MAY2018 (79)	Visit/Procedure Required	The site staff did not draw the immunological (PBMC) marker at cycle 3 day 1 (28 Mar 2018).	Non-Key
	03MAY2018 (79)	Visit/Procedure Required	The site staff did not draw the immunological (flow) marker on 28 Mar 2018 (Cycle 3 Day 1). The SC stated that the satellite site did not have the complete kit at the time of the lab draw. The SCindicated that a new lab person has been hired and is currently being trained to the study.	Non-Key
	14OCT2019 (608)	Visit/Procedure Required	PBMC Immunological sample was not collected at the Post-Treatment +60-days visit.	Non-Key
	14OCT2019 (608)	Visit/Procedure Required	Post-Carboplatin/pre-Gemcitabine and post-Gemcitabine infusion vital sign assessments were not completed at the Cycle 2 Day 1 visit.	Non-Key
	14OCT2019 (608)	Visit/Procedure Required	Post-Carboplatin/pre-Gemcitabine infusion vital sign assessment was not completed at the Cycle 2 Day 8 visit.	Non-Key
1128001	08MAR2018 (50)	Visit/Procedure Required	Immunological (PBMC) Marker is inadvertently not collected during Cycle 1 Day 1 visit on 18Jan2018.	Non-Key
	11APR2018 (84)	Laboratory	Cycle 2 Day 1 on 15-Feb-2018 the LDH lab assessment was not performed.	Non-Key
	16MAY2018 (119)	Laboratory	Inorganic Phosphorus was not performed during Cycle4Day1 Visit on 19Apr2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1128001	16MAY2018 (119)	Laboratory	LDH was not performed during Cycle4Day1 Visit on 19Apr2018.	Non-Key
	15JUN2018 (149)	Dosing	Gem was reduced at C2D1 due to 2nd case of neutropenia on 08/Feb/18. However, Feb 8th was not a dosing day, therefore, would not meet criteria for dose modifications.	Non-Key
	11SEP2018 (237)	Visit/Procedure Required	Post Carboplatin/Pre Gemcitabine and Post Gemcitabine Vitals were not collected for C3D1 on 15Mar2018 and C4D1 on 19Apr2018. Pre Carboplatin Vitals and Post Gemcitabine vitals were not collected atC4D8 on 26Apr2018.	Non-Key
1129001				
1131005	21JAN2018 (146)	Visit/Procedure Required	The FACT-A questionnaire was not completed by the subject during the visit.	Non-Key
	21JAN2018 (146)	Visit/Procedure Required	The subject did not complete the FACT-B questionnaire	Non-Key
	03APR2018 (218)	Laboratory	Hematology labs were not done for C2D15 (03Oct2017).	Non-Key
	26JUN2018 (302)	Visit Schedule	Visit C8D1 on 25Jan2018 was completed 2 days out of window. The visit should have occurred on 23Jan2018.	Non-Key
	18JUL2018 (324)	Visit/Procedure Required	The site completed a PET CT Scan and not a bone scan at screening visit dated 17-Aug-2017.	Non-Key
	03SEP2018 (371)	Concomitant Medications	The subject received GCSF 24 hours before receiving G1T28 at C2D8 on 26Sept2017.	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1131006	01MAR2018 (162)	Visit/Procedure Required	Post-Treatment Visit 2 +60-days was projected for 08-14Dec2017, but the visit did not occur.	Non-Key
	03APR2018 (195)	Laboratory	LDH and Phosphate were not done with the chemistry labs at PTV#1 (02Nov2017).	Non-Key
	29JUL2018 (312)	Enrollment Criteria	A screening brain scan was not done during the screening period. Screening visit was on 15-Sept-2017.	Key
	22SEP2019 (732)	Visit/Procedure Required	Post Carboplatin and post Gemcitabine temperatures were not taken at C1D1 (21/Sep/2017).	Non-Key
1131013	05APR2018 (23)	Visit/Procedure Required	Cycle 1 Day 1 (14-Mar-2018) Cycle 1 Day 8 (21-Mar-2018), Cycle 2 Day 1 (04-Apr-2018) Cycle 2 Day 8 (11-Apr-2018) Cycle 4 Day 1 (16-May-2018) and Cycle 4 Day 8 (23-May-2018)post-Gemcitabine/pre-Carboplatin and post carboplatin infusion vital sign assessment was not completed.	Non-Key
	24JUL2018 (133)	Laboratory	The pt. 1131-013 did not come for their Cycle 4 Day 15 on 30May2018. The hematology labs were not done.	Non-Key
	24JUL2018 (133)	Visit Schedule	PT. 1131-013 Cycle 6 Day 8 happened on 05July2018 was delayed 1 day due to Independence Day Holiday on 04July2018.	Non-Key
	22AUG2018 (162)	Visit/Procedure Required	On 25-Jul-2018, Cycle 7 Day 8 post-Gemcitabine and post-Carboplatin infusion vitals signs were not completed.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1131013	12SEP2018 (183)	Laboratory	Phosphorous was not assessed at Screening (19Feb2018)and C1D1 (14Mar2018).	Non-Key
	18JAN2019 (311)	Visit/Procedure Required	Cycle 15 Day 1 (02Jan2019) post-Gemcitabine infusion vitals signs were not recorded.	Non-Key
	18JAN2019 (311)	Visit/Procedure Required	Cycle 15 Day 8 (09Jan2019) post-Gemcitabine infusion vital signs were not recorded.	Non-Key
	11MAR2019 (363)	Dosing	Protocol treatment administered following dose skip on Cycle 16 Day 8 (13-Feb-2019), which should have resulted in subject permanent discontinuation as maximum dose modifications had been reached.	Key
	08AUG2019 (513)	Dosing	Gem dose reduced at C11D1 (10OCT2018) however pt did not meet protocol requirements for dose reduction. Per source, dose reduction were made based on C10D15 Grade 3 neutropenia 3-8OCT2018. Perprotocol, dosing modifications are only made from Day 1 labs.	Non-Key
1131015	05APR2018 (31)	Informed Consent	Informed Consent (ICF) administered on 26-Feb-2018 using the incorrect ICF template. The patient was consented using v4.0 (IRB approved 19Oct2017) when the updated Main ICF v4.2 (IRB approved05Feb218) should have been used.	Key
	05APR2018 (31)	Visit/Procedure Required	Cycle 1 Day 1 (06-Mar-2018) temperature not recorded for post-Carboplatin vital signs assessment.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1131015	05APR2018 (31)	Visit/Procedure Required	Cycle 1 Day 1 (06-Mar-2018) temperature not recorded for post-Gemcitabine/pre-Carboplatin vital signs assessment.	Non-Key
	05APR2018 (31)	Visit/Procedure Required	Cycle 1 Day 8 (13-Mar-2018) post-Carboplatin vital signs assessment was not completed.	Non-Key
	05APR2018 (31)	Visit/Procedure Required	Cycle 1 Day 8 (13-Mar-2018) temperature not recorded for post-Gemcitabine/pre-Carboplatin vital signs assessment.	Non-Key
	05APR2018 (31)	Visit/Procedure Required	Cycle 2 Day 1 (27-Mar-2018) post-Carboplatin vital signs assessment was not completed.	Non-Key
	05APR2018 (31)	Visit/Procedure Required	Cycle 2 Day 1 (27-Mar-2018) respiratory rate not recorded for post-Gemcitabine/pre-Carboplatin vital signs assessment.	Non-Key
	05APR2018 (31)	Visit/Procedure Required	Cycle 2 Day 1 (27-Mar-2018) temperature not recorded for post-Gemcitabine/pre-Carboplatin vital signs assessment.	Non-Key
	27APR2018 (53)	Laboratory	Cycle 2 Day 15 (10-Apr-2018) Hematology lab assessment was not completed.	Non-Key
	27APR2018 (53)	Visit/Procedure Required	Cycle 2 Day 8 (03-Apr-2018) post-Carboplatin infusion vital sign assessment was not completed.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1131015	27APR2018 (53)	Visit/Procedure Required	Cycle 2 Day 8 (03-Apr-2018) post-Gemcitabine/pre-Carboplatin vital sign assessment was not completed.	Non-Key
	22AUG2018 (170)	Dosing	Gemctiabine dose reduced to 400 mg/m2 for Cycle 8 Day 1 (10-Jul-2018) and Day 8 (17-Jul-2018). Source from 31-Jul-2018 confirms treating physician aware of dosing error, and Gemcitabine dose basiscorrected for Cycle 9.	Non-Key
	22AUG2018 (170)	Visit/Procedure Required	Cycle 10 Day 1 (21-Aug-2018) post-Carboplatin infusion vital signs assessment was not completed.	Non-Key
	22AUG2018 (170)	Visit/Procedure Required	Cycle 9 Day 8 (07-Aug-2018) post-Carboplatin infusion vital signs assessment was not completed.	Non-Key
	01NOV2018 (241)	Dosing	Cycle 13 Day 1 (16Oct2018) dosing administered when subject should have been discontinued following dose skip on 09Oct2018.	Key
	01NOV2018 (241)	Visit/Procedure Required	Cycle 12 Day 1 (02Oct2018) post-Gemcitabine vitals signs were not recorded.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1131015	09JUL2019 (491)	Visit Schedule	Tumor Assessments not completed on 04FEB2019 (+/-7 days). Patient continued on Gemcitabine after study discontinuation, per protocol, tumor assessments should occur every 12 weeks Â± 7 days (beginningWeek 39) thereafter, until the occurrence of disease progression, withdrawal of consent, the initiation of subsequent anticancer therapy, or study completion.	Non-Key
	09JUL2019 (491)	Visit/Procedure Required	Post-Treatment Visit 2 (+60 days)Immunologic Markers in Blood not collected on 24Dec2018.	Non-Key
1131016	13JUN2019	Visit/Procedure Required	Screening bone scan not performed. (5 Mar 2018)	Non-Key
1133001	17JUL2017 (22)	Visit/Procedure Required	Site staff administered FACT-An & B questionnaire to patient 1133-001 during Cycle 1 Day 15 visit. According to Protocol Amendment 1 v2.0, the FACT-An & B questionnaire is to be administered duringthe Day 1 visit of each cycle.	Non-Key
	27SEP2017 (94)	Visit/Procedure Required	Subject 1133-001 Cycle 3 Day 1 (14Aug2017) post-Carboplatin vitals assessments were not completed.	Non-Key
	11DEC2017 (169)	Visit Schedule	Cycle 6 Day 1 (30-Oct-2017) FACT An & B questionnaires were completed out of window on 23-Oct-2017.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1133001	25JAN2018 (214)	Visit/Procedure Required	Cycle 3 Day 8 (21Aug2017) Pre-Gemcitabine, post-Gemcitabine/pre-Carboplatin, and post-Carboplatin vitals assessments were not completed.	Non-Key
	01FEB2018 (221)	Visit Schedule	PTV #1 Immunologic FLOW sample taken out of window on 29Nov2017.	Non-Key
	01FEB2018 (221)	Visit Schedule	Post-Treatment Visit 1 (20-Nov-2017) FACT An & B questionnaire were completed out of window on 27-Nov-2017.	Non-Key
	01FEB2018 (221)	Visit/Procedure Required	Post-Treatment Visit 1 (20-Nov-2017) ECG was not completed.	Non-Key
	02MAR2018 (250)	Visit/Procedure Required	Post-Treatment Visit 2 (+60-days) FLOW immunological samples was not collected.	Non-Key
	02MAR2018 (250)	Visit/Procedure Required	Post-Treatment Visit 2 (+60-days) PBMC immunological sample was not collected.	Non-Key
	23AUG2018 (424)	Concomitant Medications	Subject should have started prophylactic use of GCSF at C3D1 (14Aug2017) due to a Gr3 Neutropenia but did not.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1133004	11DEC2017 (12)	Visit/Procedure Required	Cycle 1 Day 1 vital assessments were not completed according to the protocol. The respiratory rate was not recorded for all 3 time-points (pre-Gemcitabine, post-Gemcitabine/pre-Carboplatin, andpost-Carboplatin), and patient temperature was note recorded for 2 of the required time-points (post-Gemcitabine/pre-Carboplatin and post-Carboplatin).	Non-Key
	20SEP2018 (295)	Enrollment Criteria	The subject's screening (20Nov2017) creatine was 1.6 mg/dL which is in violation of inclusion #9 which require creatine to be less than or equal to 1.5mg/dl	Key
1137001	18JAN2018 (99)	Visit Schedule	Cycle 4 Day 1 (14Dec2017) hematology lab conducted out of window on 12Dec2017.	Key
	18JAN2018 (99)	Visit/Procedure Required	Cycle 3 Day 1 (22Nov2017) FLOW immunologic lab sample was not collected.	Non-Key
	18JAN2018 (99)	Visit/Procedure Required	Cycle 3 Day 1 (22Nov2017) PBMC immunologic lab sample was not collected.	Non-Key
	15FEB2018 (127)	Visit Schedule	Cycle 5 Day 15 (16-Jan-2018) completed 2 days out of window. Visit was due on 18Jan2018.	Non-Key
	03APR2018 (174)	Laboratory	Eosinophils were not done with the safety labs at C2D8 (09-Nov-2017)	Non-Key
	03APR2018 (174)	Laboratory	Phosphate was not done with the clinical chemistry labs for C6D1 (01-Feb-2018)	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1137001	19JUL2018 (281)	Laboratory	Lactate Dehydrogenase was not reported on the Comprehensive Metabolic Panel take during Cycle 11 Day 1 (31-May-2018).	Non-Key
	19JUL2018 (281)	Visit/Procedure Required	Cycle 11 Day 8 (07-Jun-2018) post-Carboplatin infusion vital signs were collected at 11:00 during the Carboplatin infusion (10:31-11:05).	Non-Key
	13JUN2019 (610)	Visit Schedule	Cycle 3 Day 1 projected for 16Nov2017 was conducted out of window on 22Nov2017.	Non-Key
1145001	28MAR2018 (91)	Visit/Procedure Required	Cycle 1 Day 1 blood sample collected for immunological (PBMC) marker not collected on 28DEC2017.	Non-Key
	28MAR2018 (91)	Visit/Procedure Required	Cycle 3 Day 1 blood sample not collected for immunological (PBMC) marker and immunological (flow) on 08FEB2018.	Non-Key
	30MAR2018 (93)	Laboratory	Cycle 3 Day 1 Phosphorous and LDH test not completed on 07FEB2018.	Non-Key
	02MAY2018 (126)	Visit/Procedure Required	Post-Treatment Visit 1 PBMC and FLOW immunological samples were not collected.	Non-Key
	14AUG2018 (230)	Laboratory	Clinical Chemistry Post-Treatment Visit 1-LDH and Phosphorus not completed on 21MAR2018.	Non-Key
	02JUL2019 (552)	Concomitant Medications	G-CSF was not administered for AE neutropenia despite low ANC at C1D8 & C2D8.	Non-Key
	09APR2020 (834)	Visit/Procedure Required	Post-Treatment +60-day visit PBMC and FLOW immunological samples were not collected.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1148005	02JAN2018 (-1)	Visit Schedule	patient 1148005 was not dosed within randomization window due to antibiotic administration; dosing was delayed for 10 days	Non-Key
	16JAN2018 (14)	Dosing	On C1D1 PI calculated dose for Carboplatin to a target AUC 2, but it was higher than 300 mg. On C1D1 it was administered 341 mg of Carboplatin. PI noticed this dosing error between C1D1 and C1D8 andhe corrected the dose to 294 mg of Carboplatin on C1D8.	Key
	30APR2018 (118)	Informed Consent	GCP deviation occurred for subjects 1148005, since ICF, version 4.0, dated 28 Jan 2018. was not signed on the first visit folowing approval.	Key
1154002	21JUN2018 (148)	Laboratory	On C3D1 basophiles were not performed. It was omission of laboratory staff.	Non-Key
	13AUG2018 (201)	Visit Schedule	Sub Investigator scheduled for patient 002, PTV2 visit 10 days before it was predicted by protocol amendment #3. Instead of 19Jun it was performed on 09Jun.	Non-Key
1156001	24AUG2018 (242)	Dosing	Dose Reduction for patient 001 were not performed in accordance with study protocol: at C5D1 carbo was not reduced; C5D8 was skipped due to Hem tox and again Carbo dose was not reduced.	Non-Key
	09AUG2019 (592)	Visit/Procedure Required	For patient 1156001 quadantectomy without disease progression has been done.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1156007				
1163002	22DEC2017 (37)	Laboratory	Site staff has ommitted to withdraw and send the samples for PBMC Whole Blood Samples to the central lab BST, during C1D1, performed on 16.Nov.2017	Non-Key
	22DEC2017 (37)	Visit/Procedure Required	Vital signs after trilaciclib/before Gem; and after Gem/before Carboplatin were not taken during C1D1, on 18.Nov.2017	Non-Key
	22FEB2018 (99)	Visit/Procedure Required	For pt 1163002, Tumor assessment was not performed on 07Feb2018 as the CT was not functioning. It was performed on 27Feb2018, with 19 days of delay.	Non-Key
	03SEP2018 (292)	Visit Schedule	Post Treatment visit for 1163002 was done later due to private matters of patient (on 25/Jul/2018 instead of 28/Jun/2018).	Non-Key
	16NOV2018 (366)	Visit/Procedure Required	Since the CT machine was out of order, patient could not undergo the study procedure on time. Tumor assessment was performed on 01 Mar 2018 which is 9 weeks after previous tumor assessment (performedon 28 Dec 2018). Due date for tumor assessment was 08 February 2018 ± 7 days.	Non-Key
1163006	03SEP2018 (159)	Laboratory	Thrombocytopenia for 1163006 was reported as AE#3 on 05/Jul/2018 (C5D15) and was not followed on 12/Jul/2018, as patient requested one week off due to vacation.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: GC Therapy D1D8				
1163006	17APR2019 (385)	Laboratory	For pt.1163006, AEs from C14D15 were not followed weekly.	Non-Key
	05JUN2019 (434)	Dosing	Reduction of Carbo dose not done according to protocol for pt.1163006 at C17D1	Non-Key
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1111001	05MAR2018 (132)	Visit/Procedure Required	Vitals not obtained in between and immediately after infusion on Cycle 1 Day 1 (25OCT2017)	Non-Key
	05MAR2018 (132)	Visit/Procedure Required	Vitals not obtained in between and immediately after infusion on Cycle 1 Day 8 (01NOV2017)	Non-Key
	25APR2018 (183)	Laboratory	Cycle 2 Day 1 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 07NOV2017.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 2 Day 15 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 21NOV2017..	Non-Key
	25APR2018 (183)	Laboratory	Cycle 2 Day 8 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 14NOV2017.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1111001	25APR2018 (183)	Laboratory	Cycle 3 Day 15 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 12DEC2017.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 3 Day 8 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 05DEC2017.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 3 Day 8 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 05DEC2017.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 4 Day 15 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 02JAN2018.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 4 Day 8 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 26DEC2017.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 5 Day 1 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 09JAN2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1111001	25APR2018 (183)	Laboratory	Cycle 5 Day 15 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 23JAN2018.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 5 Day 8 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 16JAN2018.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 6 Day 1 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 30JAN2018.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 6 Day 15 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 14FEB2018	Non-Key
	25APR2018 (183)	Laboratory	Cycle 6 Day 8 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 06FEB2018.	Non-Key
	25APR2018 (183)	Laboratory	Cycle 7 Day 1 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 20FEB2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1111001	25APR2018 (183)	Laboratory	Cycle 7 Day 8 Eosinophils (absolute), Basophils (absolute), Eosinophils (percentage) and Basophils (percentage) lab values missed on 27FEB2018.	Non-Key
	07JUN2018 (226)	Visit/Procedure Required	Post-Treatment Visit 1 ECG not completed on 22MAR2016.	Non-Key
	07JUN2018 (226)	Visit/Procedure Required	Post-Treatment Visit 1 Urinalysis not completed on 22MAR2018.	Non-Key
	07JUN2018 (226)	Visit/Procedure Required	Post-Treatment Visit 1 questionnaires not completed on 22MAR2018.	Non-Key
	20JUL2018 (269)	Visit/Procedure Required	Post-Treatment Visit 2 (+60 days) not completed 22MAY2018	Non-Key
	03AUG2018 (283)	Visit/Procedure Required	The FACT A & FACT B were not completed at PTV #1 on 22Mar2018	Non-Key
1111003	29JUL2018 (224)	Visit Schedule	C1D8 on 26Dec2017 was conducted 1 day out of window due to the Christmas holiday.	Non-Key
	29JUL2018 (224)	Visit Schedule	C2D8 was completed on 16Jan2018 which was one day out of window. The visit should have been done on 15Jan2018	Non-Key
	29JUL2018 (224)	Visit Schedule	C9D15 was done on 22June2018 which was 4 days out of window. Visit should have been completed on 18June2018.	Non-Key
	19AUG2018 (245)	Concomitant Medications	At C3D8, on 05Feb2018, Subject 1111-003 had a Gr3 Neutropenia, which caused a dose delay,but was not started on GCSF at later cycles .	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1111003	20MAY2019 (519)	Concomitant Medications	Growth Factor administered 10-13JAN2019 not stopped 48 hours prior to trilaciclib administration on Cycle 19 Day 8 on 14JAN2019.	Key
	20MAY2019 (519)	Visit Schedule	Cycle 20 Day 15 Hematology labs on 11FEB2019 out of window. Day 15 safety labs taken 2 days earlier than anticipated (14FEB2019 +/- 1 day).	Non-Key
	20MAY2019 (519)	Visit/Procedure Required	Cycle 20 Day 1 Post gemcitabine vitals not taken on 30JAN2019.	Non-Key
	20MAY2019 (519)	Visit/Procedure Required	Cycle 21 Day 8 vitals not taken after gemcitabine infusion on 25FEB19.	Non-Key
	21MAY2019 (520)	Visit/Procedure Required	Cycle 22 Day 1 vitals not taken after gemcitabine infusion on 18MAR2019.	Non-Key
	21MAY2019 (520)	Visit/Procedure Required	Cycle 23 Day 8 vitals not taken after gemcitabine infusion on 15APR2019.	Non-Key
	21MAY2019 (520)	Visit/Procedure Required	Cycle 24 Day 1 vitals not taken after gemcitabine infusion on 29APR2019.	Non-Key
	21MAY2019 (520)	Visit/Procedure Required	Cycle 24 Day 8 vitals not taken after gemcitabine infusion on 06MAY2019.	Non-Key
	17JUL2019 (577)	Visit/Procedure Required	Cycle 23 Day 1 vitals not taken after gemcitabine infusion on 08APR2019.	Non-Key
	17JUL2019 (577)	Visit/Procedure Required	Cycle 25 Day 1 vitals not taken after gemcitabine infusion on 20MAY2019.	Non-Key
	17JUL2019 (577)	Visit/Procedure Required	Cycle 25 Day 8 vitals not taken after gemcitabine infusion on 28MAY2019.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1111003	17JUL2019 (577)	Visit/Procedure Required	Cycle 26 Day 1 vitals not taken after gemcitabine infusion on 10JUN2019.	Non-Key
	17JUL2019 (577)	Visit/Procedure Required	Cycle 26 Day 8 vitals not taken after gemcitabine infusion on 17JUN2019.	Non-Key
	17JUL2019 (577)	Visit/Procedure Required	Cycle 27 Day 1 vitals not taken after gemcitabine infusion on 01JUL2019.	Non-Key
	13AUG2019 (604)	Dosing	Carbo was discontinued as a result of AE Platelet Count Decreased (23 Jan 2019). However the AE did not occur on a dosing day. No dose modification was required.	Non-Key
	14AUG2019 (605)	Visit/Procedure Required	Cycle 28 Day 1 vitals not taken after gemcitabine infusion on 22JUL2019.	Non-Key
	30AUG2019 (621)	Dosing	Site incorrectly reduced both Gem and Carbo at C19D1 on 07JAN2019 because of AE Neutropenia on 31/Dec/2018.	Key
	12SEP2019 (634)	Visit/Procedure Required	Cycle 28 Day 1 FACT An/B Questionnaire noted completed on 22JUL2019.	Non-Key
	12SEP2019 (634)	Visit/Procedure Required	Cycle 29 Day 1 vitals not taken after gemcitabine infusion on 12AUG2019.	Non-Key
	03OCT2019 (655)	Informed Consent	Subject 1111-003 was not consented to ICF Version 5 dated 01FEB2019 in a timely manner. Subject did not sign re-consent until 12AUG2019.	Key
1112002	19APR2017 (72)	Laboratory	Urinalysis laboratory sample not collected for Patient 1112-002 during the Screening visit on 06 Feb 2017.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1112002	19APR2017 (72)	Visit/Procedure Required	Immunological samples were not collected during Patient 1112-002 Cycle 1 Day visit on 07 Feb 2017. These lab kits were not available to the site on the day of the visit.	Non-Key
	18MAY2017 (101)	Dosing	Carboplatin infusion during Cycle 5 Day 1 (18-Apr-2017) was administered over a 16 minute time period. Per the Protocol, Carboplatin infusion should be administered over a 30-minute time period.	Non-Key
	18MAY2017 (101)	Visit/Procedure Required	Post-Carboplatin/pre-Gemcitabine vitals assessment was not completed during the Cycle 1 Day 8 (14-Feb-2017) visit.	Non-Key
	18MAY2017 (101)	Visit/Procedure Required	Post-Carboplatin/pre-Gemcitabine vitals assessment was not completed during the Cycle 3 Day 1 (14-Mar-2017) visit.	Non-Key
	18MAY2017 (101)	Visit/Procedure Required	Vitals taken at Cycle 4 Day 8 (11-Apr-2017) were taken without measuring patient Blood Pressure.	Non-Key
	10AUG2017 (185)	Visit Schedule	Cycle 9 tumor assessment completed out-of-window. According to the protocol, following cycle 6, patient tumor assessments are to be completed every 3 cycles. The cycle 9 tumor assessment for patient002 was completed a full cycle early on C8-D15 (11-Jul-2017).	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1112002	10AUG2017 (185)	Visit/Procedure Required	C9-D8 (20-Jul-2017) vital assessments not taken for post-G1T28/pre-Carboplatin or post-Gemcitabine infusions.	Non-Key
	03APR2018 (421)	Laboratory	The site did not assess inorganic phosphate at any time during the subjects participation starting at screening on 06-Feb-2017 through PTV#1 on 08-Aug-2017.	Key
1112004	18MAY2017 (73)	Dosing	Per the Protocol, patients are required to undergo Cycle 1 Day 1 treatment within 3 days from patient randomization. Patient 004 underwent Cycle 1 Day 1 treatment on 07-Mar-2017, which was 4 days frompatient randomization.	Non-Key
	18MAY2017 (73)	Visit Schedule	On Cycle 1 Day 1 (07-Mar-2017) the following PK laboratory samples were taken out of window: 0.5 hr (24 minutes early) 3.0hr (35min late) 4.5 (35 minutes early), and 6.0 hour (35 Minutes early). TheCRC did not understand the collection time points were to be collected based on the end of the infusion time.	Non-Key
	18MAY2017 (73)	Visit/Procedure Required	Post-Gemcitabine vitals assessment was not completed during the Cycle 1 Day 1 (07-Mar-2017) visit.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1112004	03APR2018 (393)	Non-compliance	The site did not assess Inorganic Phosphorous at any time during the subjects participation from C1D1 (21-Feb-2017) through EOS (16-Jun-2017)	Key
	25MAY2018 (445)	Concomitant Medications	Subject 1112-004 experienced two Grade 3 AEs for "decreased Neutrophil count" The first occurred on C1D15 and the second at C2D8. There were other graded 3 heme tox adverse events at C2D3 (decreasedWBC and decreased lymphocytes,) The patient should have started on G-CSF at this time.	Non-Key
1113001	15AUG2017 (22)	Visit/Procedure Required	PBMC Immunology blood sample not collected during patient 1113-001's C1-D1 visit on 25-Jul-2017. The study coordinator was not familiar with the lab procedures for the study. The SC was retrained bythe monitor	Non-Key
	14SEP2017 (52)	Dosing	Cycle 1 Day 1 dosing was conducted >3 days from patient 1113-001 randomization. The patient had met all inclusion criteria for the trial and was randomized on 20-Jul-2017. C. Watt, CRC, realized afterrandomization that there was no availability in the site's infusion bay to accommodate C1D1 dosing within the 3-day protocol window. This visit was 2 days out of window.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1113001	20SEP2017 (58)	Visit Schedule	Per protocol schedule of assessments, the physical exam for Cycle 1 Day 1 (C1-D1) should be performed on the same day as C1-D1 treatment. Patient 1113-001 C1-D1 physical exam was completed on24-Jul-2017 prior to C1-D1 treatment on 25-Jul-2017.	Non-Key
	26OCT2017 (94)	Visit/Procedure Required	Patient 1113-001 Cycle 3 Day 1 vital assessments were not recorded post-G1T28/pre-Gemcitabine, post-Gemcitabine/pre-Carboplatin, and post-Carboplatin infusions.	Non-Key
	27NOV2017 (126)	Visit/Procedure Required	Cycle 4 Day 8 (09-Oct-2017) vitals assessment not recorded post-G1T28 infusion. Pre-dose vitals were collected	Non-Key
	16JAN2018 (176)	Visit/Procedure Required	Cycle 7 Day 8 (11Dec2017) post-G1T28/pre-Gemcitabine vital sign assessments not performed.	Non-Key
	03APR2018 (253)	Laboratory	The Eosinophils and Basophils were not done with the hematology labs for C1D15 (07Aug2017)	Non-Key
1113004	16JAN2018 (64)	Visit/Procedure Required	Cycle 3 Day 8 (03Jan2018) post-Carboplatin vital signs were not assessed.	Non-Key
	03APR2018 (141)	Laboratory	Basophils and Eosinophils were not done as part of the hematology labs for C4D8 on 23-Jan-2018	Non-Key
	03APR2018 (141)	Laboratory	Basophils were not assessed as part of the hematology labs for C4D1 on 16-Jan-2018	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1113004	03APR2018 (141)	Laboratory	Basophils were not assessed with the hematology labs for C5D8 on 14-Feb-2018.	Non-Key
	03APR2018 (141)	Laboratory	Eosinophils and Basophils were not done as part of the hematology labs for C3D8 on 03-Jan-2018.	Non-Key
	30JUL2018 (259)	Visit/Procedure Required	C2D15 should have been completed on 20-Dec-2017 but was not done.	Non-Key
1117003				
1117004	16SEP2018 (228)	Concomitant Medications	The subject's C5D8 dose was held on 19Apr2018 due to a low ANC. Subject received GCSF during cycle 6 for prophylaxis but did not continue to receive it at subsequent cycles.	Non-Key
	17SEP2018 (229)	Laboratory	Post-Treatment Visit 2 (28Jul2018) immunologic FLOW and PBMC samples were not collected.	Non-Key
	30APR2019 (454)	Laboratory	C7D15 (24May2018) â€“ Hematology not done	Non-Key
1121001	10JAN2018 (237)	Visit/Procedure Required	C3D1 (29Jun2017) Immunology Sample was not received at BST. The site did not collect this sample.	Non-Key
	28MAR2018 (314)	Visit/Procedure Required	Immunologic, BST, Flow and PBMC samples were not collected at the post treatment visits.	Non-Key
	08APR2020 (1056)	Laboratory	Immunologic Flow and PBMC samples were not collected at Cycle 1 Day 1 on 19MAY2017.	Non-Key
1122001	27OCT2017 (24)	Dosing	The study nurse modified the dose of G1T24-04 at the C2D1 on 25Oct2017 visit.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1122001	06FEB2018 (126)	Visit/Procedure Required	The VS were not done at Post dose Carboplatin/ Predose Gemcitabine from cycle 2 day thru cycle 6 day 1. Protocol deviations must be competed and provided to the monitor to review at the nextmonitoring visit.	Non-Key
	15FEB2018 (135)	Laboratory	C2D15 (08Nov2017) CBC and CMP ordered, lab failed to collect.	Non-Key
	15FEB2018 (135)	Laboratory	On C5D15, 17Jan2018, the CBC was drawn but was not able to be used by the lab	Non-Key
	07SEP2018 (339)	Laboratory	The phosphorous and LDH were not assessed at C3D1 (15Nov2017) and C4D1 (13Nov2017).	Non-Key
	12SEP2018 (344)	Visit Schedule	Subject had an AE on 22Nov2017 for C3D8 which should have happened on 22Nov2018. The site delayed the visit to 29Nov2018. This visit should have been C4D1 instead of C3D8. C3D15 was done on 06Dec2017.	Non-Key
	18SEP2018 (350)	Dosing	The site reduced the dose of Gemcitabine to 800mg/m2 on 29Nov2018 (delayed C3D8 now C3D15) when they should not have. The subject had only had one hemetolgical toxicity at a D8.	Non-Key
	21NOV2018 (414)	Laboratory	Neu, Bas, Lymp and Mon (Absolutes) Not done on C16D8 (29Aug2018), on C17D8 (19Sep2018), C18D8 (10Oct2018), C20D8 (21Nov2018), on C22D8 (02Jan2019) and on C33D15 (04Sep2019)	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1122001	19DEC2018 (442)	Visit/Procedure Required	C18D1 FACT-An and FACT-B questionnaires not done	Non-Key
	22FEB2019 (507)	Visit/Procedure Required	Time point for Vital Signs not recorded at C24D1 (06Feb2019)	Non-Key
	04SEP2019 (701)	Dosing	There was a >4 week lapse between doses during C27 (between C26 and C28). Per protocol, this is allowed with medical monitor approval. The site confirmed that medical monitor approval was not given	Non-Key
	20DEC2019 (808)	Visit/Procedure Required	An immunological (flow) marker sample was not collected at the Post Treatment Visit 2 (+60 days) nor where Hematology Labs Collected.	Non-Key
1124002	19APR2018 (93)	Visit/Procedure Required	The Immunologic Markers in Blood (PBMC/Flow)- Post-Treatment Visit 1 dated 05 Mar 2018 were not completed.	Non-Key
	19APR2018 (93)	Visit/Procedure Required	The Post dose Gemcitabine vitals were not completed at the Cycle 1 Day 8 (24/Jan/2018) visit.	Non-Key
	13AUG2019 (574)	Visit/Procedure Required	C1D1 (17 Jan 2018) PBMC Sample not received at central lab.	Non-Key
1125001	17FEB2018 (193)	Visit/Procedure Required	The Vital Signs for Post dose Carboplatin/ Predose Gemcitabine were not completed at cycle 2 day 8 on 30Aug2018.	Non-Key
	17FEB2018 (193)	Visit/Procedure Required	The Vital Signs for Post dose Carboplatin/ Predose Gemcitabine were not completed at cycle 3 day 8 on 20-Sept-2017	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1125001	17FEB2018 (193)	Visit/Procedure Required	The site staff did not collect the immunological (PBMC) marker at cycle 5 day 1 on 01Nov2017	Non-Key
	09MAR2018 (213)	Visit/Procedure Required	The vital signs for post dose G1T2888/Predose Carboplatin not completed for C8D8 on 10Jan18.	Non-Key
	09MAR2018 (213)	Visit/Procedure Required	vitals not completed for post dose G1T2888/Predose Carboplatin for C9D1 on 24Jan18.	Non-Key
	28MAR2018 (232)	Visit/Procedure Required	The PBMC samples were not collected at C7D1, on 14Dec2017.	Non-Key
	28MAR2018 (232)	Visit/Procedure Required	The site did not collect the PBMC samples at C5D1, 01-Nov-2017.	Non-Key
	28MAR2018 (232)	Visit/Procedure Required	The site did not collect the PBMC samples for C3D1 on 20-Sept-2017	Non-Key
	04APR2018 (239)	Visit/Procedure Required	C10D1 on 07Mar18 vitals not completed for post dose G1T2888/Predose Carboplatin.	Non-Key
	04APR2018 (239)	Visit/Procedure Required	Phosphorus was not reported with the CMP at the Cycle 4 day 1 visit.	Non-Key
	20JUL2018 (346)	Visit/Procedure Required	The immunological (PBMC) marker was not done at cycle 13 Day 1 (16-May-2018).	Non-Key
	16JAN2019 (526)	Visit/Procedure Required	C11D1 PBMC sample not collected (28 March 18)	Non-Key
	14OCT2019 (797)	Visit Schedule	Cycle 15 Day 8 Hematology sample was collected >24 hours prior to Carboplatin-Gemcitabine dosing.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1125001	14OCT2019 (797)	Visit Schedule	Tumor Assessment #1 projected for 05OCT2017 (+/- 7 days) was performed out of window on 26Oct2017.	Non-Key
	14OCT2019 (797)	Visit Schedule	Tumor Assessment #4 projected for 24MAY2018 (+/- 7 days) performed out of window on 14May2018.	Non-Key
	14OCT2019 (797)	Visit/Procedure Required	FLOW Immunologic sample was not collected at the Cycle 11 Day 1 visit.	Non-Key
	14OCT2019 (797)	Visit/Procedure Required	Post-Carboplatin/pre-Gemcitabine infusion vital signs assessment was not completed for C1D8, C2D1, C2D8, C3D1, and C4D1.	Non-Key
	14DEC2019 (858)	Visit/Procedure Required	Cycle 11 Day 1 PBMC immunological samples was not collected.	Non-Key
1125007				
1125008	20JUL2018 (66)	Visit/Procedure Required	The Vitals were not taken post dose G1T28/Pre dose Carbo, Pose dose Carbo/pre dose Gem, Post dose Gem during C1D1 on 15May2018 C1D8 on 22May2018, Cycle-1 Day-8, C2D1 on 19June2018, C2D8 on 26June2018,and C3D8 on 19Jul2018 for pt. 1125-008.	Non-Key
	20JUL2018 (66)	Visit/Procedure Required	The site staff did not draw the immunological (PBMC) at Cycle 1 Day 1 (16-May-2018) for pt. 1125-008.	Non-Key
	17SEP2018 (125)	Visit Schedule	C1D8 was conducted one day early on 22May2018. 7 days after C1D1 would have been 23May2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1125008	07NOV2018 (176)	Visit/Procedure Required	C5D1 blood sample collected for immunological (PBMC) marker not collected on 23AUG2018.	Non-Key
	15NOV2018 (184)	Visit Schedule	Cycle 4 Day 15 (20AUG2018) 4 days out of window.	Non-Key
	14DEC2018 (213)	Concomitant Medications	Subject 1125-008 received G-CSF (31OCT2018) less than 48 hours prior to C8D1 on 01NOV2018. Per protocol, Short-acting G-CSF products (ie, Neupogen or biosimilars) must be stopped 48 hours prior totrilaciclib administration in Groups 2 and 3	Key
	16JAN2019 (246)	Visit/Procedure Required	C3D1 (12 July 18) PBMC sample not collected	Non-Key
	16JAN2019 (246)	Visit/Procedure Required	C5D1 (23 Aug 18) PBMC sample not collected.	Non-Key
	22JAN2019 (252)	Concomitant Medications	Subject 1125-008 received G-CSF (12DEC2018) less than 48 hours prior to C10D1 on 12DEC2018. Per protocol, Short-acting G-CSF products (ie, Neupogen or biosimilars) must be stopped 48 hours prior totrilaciclib administration in Groups 2 and 3	Key
	22JAN2019 (252)	Visit/Procedure Required	Cycle 9 Day 1 Immunologic Markers in Blood not collected on 21NOV2018.	Non-Key
	20FEB2019 (281)	Dosing	Gemcitabine not reduce at Cycle 4 Day 1 on 02AUG2018 after neutropenia caused dose skip during Cycle 3.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1125008	27FEB2019 (288)	Visit/Procedure Required	Cycle 12 Day 1 Clinical Chemistry not performed on 31JAN2019.	Non-Key
	06MAY2019 (356)	Laboratory	Cycle 13 Day 1 (28-Feb-2019) CMP assessment was not completed.	Non-Key
	06MAY2019 (356)	Visit Schedule	Cycle 12 Day 1 (31-Jan-2019) questionnaires completed out of window on 24-Jan-2019.	Non-Key
	06MAY2019 (356)	Visit Schedule	Cycle 13 Day 1 (28-Feb-2019) questionnaires completed out of window on 21-Feb-2019.	Non-Key
	06MAY2019 (356)	Visit Schedule	Post Treatment Visit 1 (21-Mar-2019) ECOG performance status was not assessed.	Non-Key
	15JUL2019 (426)	Visit Schedule	Subject 1125-008 tumor assessment projected for 07May2019 (Â±7 days) was completed out of window on 18Apr2019.	Non-Key
1126003	14MAY2018 (309)	Laboratory	Required LDH laboratory was not performed at C1D15 on 24July2017	Non-Key
	14MAY2018 (309)	Laboratory	Required LDH laboratory was not performed at PTV#2 on 07Nov2017	Non-Key
	14MAY2018 (309)	Laboratory	Required LDH laboratory was not performed on C2D1 on 31Jul2017	Non-Key
	14MAY2018 (309)	Laboratory	Required Phosphate laboratory was not performed at PTV#2 on 07Nov2017	Non-Key
	14MAY2018 (309)	Laboratory	Required Phosphate laboratory was not performed on C1D15 on 24July2017	Non-Key
	14MAY2018 (309)	Laboratory	Required Phosphate laboratory was not performed on C2D1 on 31July2017	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1126003	26JUN2018 (352)	Dosing	The infusion of carboplatin was 1 minute too long for C1D8 on 17July2017. The infusion should have been 30 minutes but took 31 minutes to complete	Non-Key
	28JUN2018 (354)	Laboratory	LDH and Inorganic Phosphorus was not performed during Post Treatment Visit 1 on 05Sep2017.	Non-Key
	28AUG2018 (415)	Visit/Procedure Required	The subject was consented to the PK arm but the C1D1 (10July2017) PK samples were not collected	Non-Key
1126004	02FEB2018 (60)	Enrollment Criteria	At screening Subject 1126004 the required CT scan of the brain prior to C1D1 was inadvertently missed.	Key
	02FEB2018 (60)	Visit Schedule	Subject 1126004 C2D1 moved 1 day due to holiday. Site received Sponsor's approval prior to scheduling.	Non-Key
	04APR2018 (121)	Visit/Procedure Required	Immunologic marker and PBMC samples were not collected during the Post Treatment Visit 2 on 27Feb2018.	Non-Key
	08MAY2018 (155)	Visit/Procedure Required	Immunologic Marker in Blood was bot performed for subject 1126004 during the Post Treatment Visit 2 on 27Feb2018.	Non-Key
	14MAY2018 (161)	Laboratory	Required Urinalysis was not performed at the screening visit on 14Nov2017	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1127001	31OCT2017 (21)	Dosing	Carboplatin Administration - Cycle 1 Day 1 administered over 1 hour 2 minute infusion. Per protocol, carboplatin should be administered over 30 minute infusions.	Non-Key
	20DEC2017 (71)	Visit/Procedure Required	The vital signs for patient 1127-001 to be taken post-Carboplatin/pre-Gemcitabine infusions were not completed during C1-D1 (11-Oct-2017)	Non-Key
	12FEB2018 (125)	Visit/Procedure Required	The vital signs for patient 1127-001 to be taken post-Carboplatin/pre-Gemcitabine infusions were not completed during C2-D1 (01-Nov-2017).	Non-Key
	17APR2018 (189)	Enrollment Criteria	The site had archival tumor at the time of screening. They have an associate pathology report. However, the sample has been lost by the site and will not be sent to BST.	Non-Key
1129005	25JAN2018 (80)	Dosing	Cycle 2 Day 8 (05Dec2017) G1T28 infusion administered when dosing should have been held due to hematologic toxicity.	Key
	21FEB2018 (107)	Dosing	Cycle 5 Day 1 (30-Jan-2018) completed out-of-window. Patient was eligible to complete Cycle 5 Day 1 visit on 23-Jan-2018, but the visit procedures and infusions were not performed.	Non-Key
	21FEB2018 (107)	Visit Schedule	Cycle 5 Day 1 (30-Jan-2018) FACT An & B questionnaires completed out-of-window on 23-Jan-2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1129005	21FEB2018 (107)	Visit Schedule	FACT An & B questionnaires completed out-of-window during Cycle 3 Day 15 visit (02-Jan-2018).	Non-Key
	21FEB2018 (107)	Visit Schedule	FACT An & B questionnaires completed out-of-window on Cycle 2 Day 15 visit (12-Dec-2017)	Non-Key
	10APR2018 (155)	Dosing	Cycle 6 Day 1 (20-Feb-2018) completed out-of-window. Patient was eligible to complete Cycle 6 Day 1 visit on 13-Feb-2018, but the visit procedures and infusions were not performed.	Non-Key
	10APR2018 (155)	Dosing	Cycle 7 Day 1 (13-Mar-2018) completed out-of-window. Patient was eligible to complete Cycle 7 Day 1 visit on 06-Mar-2018, but the visit procedures and infusions were not performed.	Non-Key
	10APR2018 (155)	Visit Schedule	FACT An & B questionnaires completed out-of-window during an unscheduled visit on 13-Feb-2018.	Non-Key
	10APR2018 (155)	Visit/Procedure Required	Cycle 7 Day 1 (13-Mar-2018) FLOW immunologic sample was not collected.	Non-Key
	10APR2018 (155)	Visit/Procedure Required	Cycle 7 Day 1 (13-Mar-2018) PBMC immunologic sample was not collected.	Non-Key
	14MAY2018 (189)	Visit Schedule	Post-Treatment Visit 1 (03-Apr-2018) immunologic FLOW sample was collected out of window on 18-Apr-2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1129005	14MAY2018 (189)	Visit Schedule	Post-Treatment Visit 1 (03-Apr-2018) immunologic PBMC sample was collected out of window on 18-Apr-2018.	Non-Key
	21AUG2018 (288)	Informed Consent	Patient 1129-005 was not re-consented using ICF v4.2 IRB approved on 05Feb2018.	Key
1131001	03APR2018 (292)	Laboratory	Hematology labs were not done for C3D15 (02Aug2018)	Non-Key
	13AUG2018 (424)	Other	Subject had new non target lesions identified at an unscheduled visiton 28June2018 This indicates progressive disease per RECIST 1.1. Subject should not have received treatment at visit C2D1 on05July2018.	Key
	21AUG2018 (432)	Dosing	Patient 1131-001 received treatment on cycle 2 day 1 with a grade 3 Hypocalcemia on (3-Jul-17) and was treated. Treatment should have been held until all AE's return to a grade 2.	Non-Key
	10MAY2019 (694)	Non-compliance	28 June 2017 Unscheduled Visit- New Lesion identified- Subject was not withdrawn from study until 2 Aug 2017.	Key
	07AUG2019 (783)	Visit Schedule	CT scans (17 May 2017) were not obtained within 28 days from the first IP dose (16 Jun2017).	Non-Key
	21SEP2019 (828)	Regulatory	Subjects 1131001 SAE (acute hypoxic respiratory failure) on 23AUG2017 not reported Within 24 HOURS.	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1131011	01MAR2018 (24)	Visit/Procedure Required	Screening Brain MRI was not performed. Source indicates physician noted there was no clinical indication for brain imaging to be completed at this time.	Non-Key
	25APR2018 (79)	Laboratory	The site staff did not collect Eosinophils (absolute), Eosinophils (percentage), Basophils (percentage)at C4D15 or 17April2018.	Non-Key
	28APR2018 (82)	Visit Schedule	The tumor assessment was done 10 days out of window. It was completed on 09Apr2018. It was due on 23Mar2018 +/-7 days.	Non-Key
	22AUG2018 (198)	Dosing	Cycle 8 Day 1 (03-Jul-2018) Gemcitbaine dose was not reduced follow first dose delay due to thrombocytopenia that began on 20-Jun-2018.	Non-Key
	28AUG2018 (204)	Dosing	Cycle 9 Day 8 (07Aug2018) was conducted when dosing should have been skipped due to decreased platelets <100 x109/L.	Key
	10DEC2018 (308)	Visit Schedule	Cycle 13 Day 8 projected for 06-Nov-2018 was conducted 1 day out of window on 07-Nov-2018.	Non-Key
	10DEC2018 (308)	Visit/Procedure Required	Cycle 13 Day 1 (30-Oct-2018) temperature for post-G1T28/pre-Gemcitabine infusion vital signs assessment was not recorded.	Non-Key
	10DEC2018 (308)	Visit/Procedure Required	Cycle 14 Day 8 (27-Nov-2018) temperature for post-G1T28/pre-Gemcitabine infusion vital signs assessment was not recorded.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1131011	18JAN2019 (347)	Visit Schedule	Cycle 16 Day 1 (02Jan2019) Hematology labs were collected out of window on 31Dec2018.	Key
	18JAN2019 (347)	Visit Schedule	Cycle 16 Day 8 was projected for 09Jan2019 was completed 1 day out of window on 08Jan2019.	Non-Key
	15MAY2019 (464)	Visit Schedule	Flow and PBMC sample not collected within 24 hours of dosing (C9D1- 31 July 18) Sample collected 24 Jul 18.	Non-Key
	07AUG2019 (548)	Dosing	Overall Progressive Disease response, but patient continued to receive study drug after 13-Dec-18, which is deviating from protocol section 12.2. Discontinuation of Study Drug.	Key
	07AUG2019 (548)	Laboratory	Clinical Chemistry 2 not completed at Post-Treatment Visit 1 on 26FEB2019.	Non-Key
	07AUG2019 (548)	Visit Schedule	PTV1 on 26FEB2019 completed out of window. Per NTF, PTV should be performed on D22 (05MAR19) of last cycle.	Non-Key
	07AUG2019 (548)	Visit/Procedure Required	Post-Treatment Visit 2 (+60 days) Immunologic Markers in Blood not completed on 16APR2019.	Non-Key
	22SEP2019 (594)	Regulatory	Subjects 1131011 was informed of a change in the 24 hour phone number listed in the ICF v4.2 (approved on 04 Apr 2018) on 22 May 2018. This was more than 30 days from IRB approval of this new consentform.	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1131014	05APR2018 (31)	Visit/Procedure Required	Cycle 1 Day 1 (06-Mar-2018) post-Carboplatin infusion vital signs were not completed.	Non-Key
	05APR2018 (31)	Visit/Procedure Required	Cycle 1 Day 1 (06-Mar-2018) post-Gemcitabine/pre-Carboplatin infusion vital signs were not completed.	Non-Key
	27APR2018 (53)	Visit/Procedure Required	Cycle 2 Day 1 (03-Apr-2018) post-Carboplatin infusion vital sign assessment was not completed.	Non-Key
	27APR2018 (53)	Visit/Procedure Required	Cycle 2 Day 1 (03-Apr-2018) post-Gemcitabine/pre-Carboplatin infusion vital sign assessment was not completed.	Non-Key
	27APR2018 (53)	Visit/Procedure Required	Cycle 2 Day 8 (10-Apr-2018) post-Carboplatin infusion vital sign assessment was not compelted.	Non-Key
	27APR2018 (53)	Visit/Procedure Required	Cycle 2 Day 8 (10-Apr-2018) post-G1T28/pre-Gemcitabine infusion vital sign assessment was not completed.	Non-Key
	27APR2018 (53)	Visit/Procedure Required	Cycle 2 Day 8 (10-Apr-2018) post-Gemcitabine/pre-Carboplatin infusion vital sign assessment was not completed.	Non-Key
	06JUN2018 (93)	Visit/Procedure Required	Cycle 3 Day 1 (24-Apr-2018) PBMC Immunological sample was collected and shipped ambient to Covance instead of Biostorage, and samples was determined to be unusable.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1131014	12SEP2018 (191)	Dosing	Subject had a gr3 low ANC on 05June2018 that resulted in a second dose delay. Gemcitabine should have been reduced to 800mg/m2 but remained at 1000mg/m2	Non-Key
	04OCT2018 (213)	Visit/Procedure Required	Cycle 8 Day 15 visit projected for 04-Sep-2018 was not conducted.	Non-Key
	04OCT2018 (213)	Visit/Procedure Required	Cycle 8 Day 8 (28-Aug-2018) heart rate was not recorded for pre-G1T28, post-G1T28, post-Gemcitabine, or post-Carboplatin infusion vital signs assessments.	Non-Key
	04OCT2018 (213)	Visit/Procedure Required	Cycle 8 Day 8 (28-Aug-2018) respiratory rate was not recorded for pre-G1T28, post-G1T28, post-Gemcitabine, or post-Carboplatin infusion vital signs assessments.	Non-Key
	10DEC2018 (280)	Dosing	Carboplatin AUC should have been reduced to 1.5 following third instance of hematologic toxicity on 09-Oct-2018, but the site did not make the require dose modification.	Non-Key
	14DEC2018 (284)	Dosing	C11 D8 Carboplatin dose was not modified following dose skip due to hematologic toxicity (ANC<1.0) on 14-Nov-2018.	Non-Key
	08JUL2019 (490)	Laboratory	Post-Treatment Visit 1 Clinical Chemistry 2 not completed on 08JAN2019.	Non-Key
	08JUL2019 (490)	Visit Schedule	Post Treatment Visit +60 (28JAN2019) performed out of window. Per protocol, visit should be performed 60 days after Post Treatment Visit on 08JAN2019.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1131014	08AUG2019 (521)	Visit/Procedure Required	Cycle 11 Day 15 visit not completed on 21NOV2018 for unknown reason.	Non-Key
	22SEP2019 (566)	Visit Schedule	Time of vital signs was not documented in the EMR, and therefore was not reported in the eCRF for pre and/or post treatment infusions at C1D1, C1D8, and C2D1.	Non-Key
1133002	09NOV2017 (30)	Non-compliance	Cycle 1 Day 15 (25Oct2017) visit was conducted using an outside facility not listed on the FDA Form 1572.	Key
	11DEC2017 (62)	Dosing	Cycle 3 Day 8 (projected 27-Nov-2017) was delayed and visit was conducted out of window on 29-Nov-2017.	Non-Key
	02MAR2018 (143)	Visit Schedule	Cycle 6 Day 15 visit projected for 07-Feb-2018 was conducted out of window on 12-Feb-2018.	Non-Key
	02MAR2018 (143)	Visit/Procedure Required	Cycle 5 Day 15 visit projected for 17-Jan-2018 was not conducted.	Non-Key
	02MAR2018 (143)	Visit/Procedure Required	Cycle 6 Day 1 (24-Jan-2018) respiratory rate not recorded for post-Carboplatin vital sign assessment.	Non-Key
	02MAR2018 (143)	Visit/Procedure Required	Cycle 6 Day 1 (24-Jan-2018) respiratory rate was not recorded for post-G1T28/pre-Gemcitabine infusion vital sign assessment.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1133002	02MAR2018 (143)	Visit/Procedure Required	Cycle 6 Day 1 (24-Jan-2018) respiratory rate was not recorded for post-Gemcitabine/pre-Carboplatin vital sign assessment.	Non-Key
	02MAR2018 (143)	Visit/Procedure Required	Cycle 6 Day 1 (24-Jan-2018) respiratory rate was not recorded for pre-G1T28 infusion vital sign assessment.	Non-Key
	28MAR2018 (169)	Other	Cycle 7 Day 15 (projected 28-Feb-2018) was not conducted. UPDATE 28-Jun-2018: Outside medical records were provided to documented the Day 15 activities (CBC) was conducted at an outside clinic,Tennessee Cancer Specialists, on 28-Feb-2018	Non-Key
	28MAR2018 (169)	Visit/Procedure Required	Cycle 7 Day 1 (14-Feb-2018) ECOG score not assessed.	Non-Key
	28MAR2018 (169)	Visit/Procedure Required	Cycle 7 Day 8 (21-Feb-2018) post-Carboplatin infusion vitals signs were not assessed.	Non-Key
	05JUL2018 (268)	Dosing	Cycle 9 Day 8 (04-Apr-2018) should have been skipped to hematologic toxicity. However, the Day 8 visit was delayed and infusions administered against the protocol on 11-Apr-2018.	Key
	05JUL2018 (268)	Visit/Procedure Required	Cycle 11 Day 1 (16-May-2018) FLOW immunologic sample was not collected.	Non-Key
	05JUL2018 (268)	Visit/Procedure Required	Cycle 11 Day 1 (16-May-2018) PBMC immunologic sample was not collected.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1133002	05JUL2018 (268)	Visit/Procedure Required	Cycle 9 Day 15 visit (projected 18Apr2018) was not conducted.	Non-Key
	05JUL2018 (268)	Visit/Procedure Required	Cycle 9 Day 8 (11-Apr-2018) PostCarboplatin/Pre Gemcitabine and Post Gemcitabine infusion vital signs assessment was not completed.	Non-Key
	17AUG2018 (311)	Informed Consent	Patient 1133-002 was not reconsented using ICF v4.2 as required by G1 Therappeutics per IB v6.0 Memo issued 20Dec2017.	Key
	17AUG2018 (311)	Laboratory	Cycle 13 Day 15 (18Jul2018) hematology lab assessment was not completed.	Non-Key
	17AUG2018 (311)	Visit/Procedure Required	Cycle 12 Day 15 visit projected 26-28Jun2018 was not conducted.	Non-Key
	17AUG2018 (311)	Visit/Procedure Required	Cycle 13 Day 1 (05Jul2018) FLOW and PBMC laboratory samples were not collected.	Non-Key
	17AUG2018 (311)	Visit/Procedure Required	The time of Cycle 13 Day 1 (05Jul2018) post-Gemcitabine/pre-Carboplatin and post-Carboplatin infusion vital sign assessments were not recorded.	Non-Key
	17AUG2018 (311)	Visit/Procedure Required	The time of all Cycle 13 Day 8 (12Jul2018) infusion vital sign assessments were not recorded.	Non-Key
	12SEP2018 (337)	Concomitant Medications	The subject had a Gr3 Neutropenia on 03Apr2018. The subject did not receive GCSF at later cycles.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1133002	12SEP2018 (337)	Visit Schedule	The C6D15 visit was conducted 5 days out of window on 12Feb2018. It should have been done on 07Feb2018.	Non-Key
	12OCT2018 (367)	Laboratory	Cycle 13 Day 15 (18Jul2018) hematology lab did not result absolute neutrophil count.	Non-Key
	12OCT2018 (367)	Visit/Procedure Required	Cycle 15 Day 15 (projected 03-05Sep2018) was not conducted.	Non-Key
	12OCT2018 (367)	Visit/Procedure Required	Time not recorded for Cycle 15 Day 1 (22Aug2018) post-G1t28/pre-Gemcitabine and post-Carboplatin infusion vital signs assessments.	Non-Key
	14JAN2019 (461)	Visit Schedule	Post-Treatment Visit +60-days (07-Nov-2018) PBMC and FLOW immunologic samples were collected out of window on 28-Nov-2018.	Non-Key
	14JAN2019 (461)	Visit Schedule	Post-Treatment Visit 1 (12-Sep-2018) PBMC and FLOW immunologic samples were collected out of window on 26-Sep-2018.	Non-Key
	10MAY2019 (577)	Visit Schedule	PTV 1 (12 Sep 2018) was conducted 7 days out of window.	Non-Key
	10MAY2019 (577)	Visit Schedule	PTV+60 (07 Nov 2108) was conducted 3 days out of window.	Non-Key
1133005	17APR2018 (28)	Visit/Procedure Required	The site staff did not collect the 1 hour and 24 hour PK samples from the C1D1 visit on 21Mar2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1133005	22MAY2018 (63)	Dosing	Cycle 1 Day 1 (21-Mar-2018) infusions administered out of order. Gemcitabine was administered prior to Carboplatin infusion when the protocol requires Carboplatin to be administered first on on PKsampling days.	Non-Key
	22MAY2018 (63)	Visit Schedule	Cycle 1 Day 1 (21-Mar-2018) 3-of-3 5.5 hour ECGs were taken out of window. The 5.5 hour ECGs were recorded at 17:22, 17:24, and 17:25. ECGs were projected to be collected starting at 17:45, or at18:12 if adjusting the collection time based on the stop and re-start if the G1T28 infusion.	Non-Key
	22MAY2018 (63)	Visit Schedule	Cycle 1 Day 1 (21-Mar-2018) 5.5 hour PK sample collected out of window. Sample collected at 17:20 when PK collection was projected for 1745 or 18:12 if the schedule was adjusted to account for stopand re-start of G1T28 infusion.	Non-Key
	22MAY2018 (63)	Visit Schedule	Cycle 1 Day 1 (21-Mar-2018) hematology lab completed out of window on 19-Mar-2018.	Key
	22MAY2018 (63)	Visit Schedule	Cycle 2 Day 1 (11-Apr-2018) hematology lab completed out of window on 09-Apr-2018.	Key
	22MAY2018 (63)	Visit/Procedure Required	Cycle 1 Day 1 (21-Mar-2018) 2-of-3 0.5 hour ECGs taken during the Gemcitabine infusion at 13:13 and 13:14.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1133005	22MAY2018 (63)	Visit/Procedure Required	Cycle 1 Day 1 (21-Mar-2018) time of the post-Carboplatin/pre-Gemcitabine infusion vital sign assessment was not recorded.	Non-Key
	22MAY2018 (63)	Visit/Procedure Required	Cycle 1 Day 1 (21-Mar-2018) time of the post-G1T28/pre-Carboplatin infusion vital sign assessment was not recorded.	Non-Key
	22MAY2018 (63)	Visit/Procedure Required	Cycle 1 Day 1 (21-Mar-2018) time of the post-Gemcitabine infusion vital sign assessment was not recorded.	Non-Key
	22MAY2018 (63)	Visit/Procedure Required	Cycle 1 Day 1 (21-Mar-2018) time of the pre-G1T28 infusion vital sign assessment was not recorded.	Non-Key
	05JUL2018 (107)	Visit Schedule	Post-Treatment Visit 1 (25-May-2018) was projected for 02-05May2018, but was conducted out of window on 25-May-2018.	Non-Key
1137002	16MAR2018 (19)	Visit Schedule	Cycle 1 Day 8 (05-Mar-2018) CBC completed out of window on 02-Mar-2018.	Key
	03APR2018 (37)	Laboratory	The safety labs were not done for C1D15 (12Mar2018).	Non-Key
	31MAY2018 (95)	Laboratory	Cycle 1 Day 15 (12-Mar-2018) CBC not completed. Source indicated blood draw was unable to be completed via port, and patient refused peripheral blood draw.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1141001	11OCT2017 (35)	Dosing	Carboplatin infusion during Cycle 1 Day 1 (07-Sep-2017) was administered over a 1 hour time period. Per the Protocol, Carboplatin infusion should be administered over a 30-minute time period for C1D1PK patients.	Non-Key
	11OCT2017 (35)	Dosing	Gemcitabine infusion during Cycle 1 Day 1 (07-Sep-2017) was administered over a 35 minute time period. Per the Protocol, Gemcitabine infusion should be administered over a 30-minute time period.	Non-Key
	12OCT2017 (36)	Dosing	Gemcitabine infusion during Cycle 1 Day 1 (14-Sep-2017) was administered over a 40 minute time period. Per the Protocol, Gemcitabine infusion should be administered over a 30-minute time period	Non-Key
	12OCT2017 (36)	Visit Schedule	Cycle 1 Day 1 (07-Sep-2017) 2.5hr, 4 hr, and 5.5 hr PK samples were taken out of window. The 2.5 hour dose was collected 1 hour out of window at 15:15. It was due at 14:15. The 4 hour dose wascollected at 16:45, 1 hour out of window. It should have been collected at 15:45. The 5.5 hour sample was collected at 18:17. This is one hour out of window.	Non-Key
	12OCT2017 (36)	Visit/Procedure Required	C1D1, 07-Sept-2017, immunological (PBMC) marker not collected.	Non-Key
	11DEC2017 (96)	Visit/Procedure Required	Patient 1141-001 FACT-B (Version 4) for Cycle 4 Day 1 not completed on 15NOV2017.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1141001	14MAR2018 (189)	Visit Schedule	Cycle 4 Day 8 Vitals (11:19) taken during Gemciatbine infusion (10:48 to 11:26) on 22NOV2017.	Non-Key
	23MAY2018 (259)	Laboratory	Post-Treatment Visit 1 Urinalysis not collected on 01MAR2018.	Non-Key
	12JUL2018 (309)	Visit/Procedure Required	Post-Treatment Visit 2 (+60 days) Immunologic Markers in Blood not collected on 18APR2018.	Non-Key
	18JUL2018 (315)	Visit/Procedure Required	Post-Treatment Visit Immunologic Markers in Blood not collected on 01MAR2018.	Non-Key
	02SEP2018 (361)	Laboratory	PTV1 (01Mar2018) clinical chemistry samples for LDH and Phosphorous were not done.	Non-Key
	10JUN2019 (642)	Dosing	Site skipped C3D8 dosing due to heme tox however the heme toxicity resolved 1 week later and subject should have been dosed at C3D15.	Non-Key
1145002	30APR2018 (40)	Visit/Procedure Required	Immunologic Markers in Blood not collected for Cycle 3 day 1 on 26APR2018.	Non-Key
	11JUN2018 (82)	Visit Schedule	Hematology (01MAY2018) obtained more than 24 hours prior to GC dosing on Cycle 3 Day 8 (03MAY2018).	Key
	11JUN2018 (82)	Visit Schedule	Hematology (15MAY2018) obtained more than 24 hours prior to GC dosing on Cycle 4 Day 1 (17MAY2018).	Key
	11JUN2018 (82)	Visit Schedule	Screening Brain Scan (09FEB2018) not completed with 28 days of dosing (22MAR2018).	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1145002	12JUN2018 (83)	Concomitant Medications	G-CSF not administered 24 to 48 hours after the dose of chemotherapy on Cycle 3 Day 1 (26APR2018) or Day 8 (03MAY2018) following neutropenia during Cycle 2 Day 8 on 18APR2018. The dose was skipped forC2D8 therefore GCSF should have been used at subsequent cycles.	Non-Key
	13JUN2018 (84)	Visit/Procedure Required	Cycle 1 Day 1 Immunologic Markers in Blood not collected on 22MAR2018.	Non-Key
	18JUN2018 (89)	Dosing	Cycle 4 Day 8 (24MAY2018) dose delayed due to low ANC. Patient received treatment for Cycle 4 Day 8 on 31MAY2018. Per protocol, if hematology criteria is not met, the Day 8 GC doses should be skipped;and the next GC doses should have become Day 1 of cycle 5.	Non-Key
	18JUN2018 (89)	Dosing	Following the second episode of low ANC toxicity on (24MAY2018) the gemcitabine was not reduced to 800 mg/m2 at Cycle 4 Day 8 (31MAY2018).	Non-Key
	25JUL2018 (126)	Concomitant Medications	G-CSF not administered 24 to 48 hours after the dose of chemotherapy on Cycle 4 Day 1 (17MAY2018) or Day 8 (31MAY2018). This should have been added following neutropenia during Cycle 2 Day 8 on18APR2018, but was missed Cycle 3 as well.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1145002	25JUL2018 (126)	Visit Schedule	Hematology (28MAR2018) obtained more than 24 hours prior to GC dosing on Cycle 1 Day 8 (29MAR2018). (Hem taken 28MAR at 8:54 AM. IP given 29MAR at 10:15 AM.)	Non-Key
	25JUL2018 (126)	Visit/Procedure Required	Cycle 1 Day 1 (22Mar2018) infusion vital signs were not taken post-G1T28, pre and post Carboplatin, and pre and post Gemcitabine.	Non-Key
	14AUG2018 (146)	Laboratory	Clinical Chemistry Cycle 3 Day 1-LDH and Phosphorus not completed on 26APR2018.	Non-Key
	14AUG2018 (146)	Laboratory	Clinical Chemistry Cycle 5 Day 1-LDH and Phosphorus not completed on 12JUN2018.	Non-Key
	14AUG2018 (146)	Laboratory	Clinical Chemistry Cycle 6 Day 1-LDH and Phosphorus not completed on 09JUL2018.	Non-Key
	14AUG2018 (146)	Visit Schedule	On Cycle 6 Day 1 (12JUL2018) out of window labs (09JUL2018) used to dose to patient. Per protocol, hematology must be obtained within 24 hours prior to dosing. Hematology and chemistry labs drawn on12JuL2018, but results not received until 13JUL2018.	Key
	31AUG2018 (163)	Visit Schedule	Cycle 8 Day 1 on 16AUG2018, the site used labs from 13AUG2018 to make dosing decisions. Labs were drawn on 16AUG2018 at 15:30 and not reported until 18AUG2018.	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1145002	31AUG2018 (163)	Visit Schedule	On Cycle 6 Day 8 (19JUL2018) out of window labs from 17JUL2018 were used to dose patient. (Hematology and chemistry labs were drawn on 19JuL2018, but results not reported unti 01AUG2018)	Key
	31AUG2018 (163)	Visit Schedule	Week 18 tumor assessments out of window. Subject 1145-002 Week 9 tumor assessments occurred 14MAY2018, therefore Week 18 tumor assessments are expected 16JUL2018 +/- 7 days. Instead the patient'sscans occured on 25JUL2018.	Non-Key
	02OCT2018 (195)	Dosing	C7D8 was skipped on 07AUG2018 due to low ANC, but Carbo was not dose reduced on C8D1.	Non-Key
	02OCT2018 (195)	Laboratory	Cycle 8 Day 1 LDH and phosphorus not collected on 13AUG2018.	Non-Key
	02OCT2018 (195)	Visit/Procedure Required	Immunologic Markers in Blood (PBMC) not collected at Cycle 9 Day 1 on 19SEP2018.	Non-Key
	02OCT2018 (195)	Visit/Procedure Required	Immunologic Markers in Blood not collected Cycle 7 Day 1 on 02AUG2018.	Non-Key
	14NOV2018 (238)	Dosing	Carbo dose not reduced on C8D1 (16AUG2018) after 3rd episode of neutropenia. C8D8 carbo reduced AUC of 1.5 on 23AUG2018.	Non-Key
	14DEC2018 (268)	Dosing	C8D8 carbo reduced AUC of 1.5 on 23AUG2018. Late dose reductions are not allowed at Day 8.	Non-Key
	10MAY2019 (415)	Visit/Procedure Required	Post dose G1T28 vitals not taken C2D8 on 18APR2018	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1145002	14MAY2019 (419)	Visit Schedule	Hematology (12JUN2018) obtained more than 24 hours prior to GC dosing on Cycle 5 Day 1 (14JUN2018).	Non-Key
1145005	21AUG2018 (100)	Visit Schedule	C2D1 on 04June2018 labs were not collected prior to treatment. C2D1 hematology and chemistry labs were collected at 15:40. G1T28 treatment began at 12:36	Key
	03OCT2018 (143)	Laboratory	LDH and Phosphorus not collected on Cycle 5 Day 1 on 06AUG2018.	Non-Key
	05OCT2018 (145)	Visit/Procedure Required	Immunologic Markers in Blood (PBMC) Cycle 5 Day 1 not collected on 08AUG2018.	Non-Key
	05OCT2018 (145)	Visit/Procedure Required	Immunologic Markers in Blood (PBMC) Cycle 7 Day 1 not collected on 05SEP2018.	Non-Key
	09OCT2018 (149)	Visit Schedule	C5D1 Hematology labs (06AUG2018) obtained more than 24 hours before dosing (08AUG2018).	Key
	09OCT2018 (149)	Visit Schedule	C5D8 Hematology labs (13AUG2018) obtained more than 24 hours before dosing (15AUG2018).	Key
	12NOV2018 (183)	Dosing	On 22AUG2018 C6D1 Gemcitabine was reduced to 800, however C5D1 was skipped for AE#1 Neutropenia and therefore GCSF should have been added instead of Gem dose reduction.	Non-Key
	09APR2020 (697)	Visit/Procedure Required	Cycle 3 Day 1 PBMC immunological samples was not collected.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1148004	16JAN2018 (51)	Dosing	The dose of Gemcitabine was not reduced to 800 mg/m2 on C2D1, after the first episode of thrombocytopenia. Administered dose of Gemcitabine was the same as for C1D1.	Non-Key
	18JAN2018 (53)	Laboratory	Samples for Covance lab were not collected on C3D1 due to missing lab kits.	Non-Key
	31JAN2018 (66)	Dosing	For subject #1148004 during calculation of dose for carboplatin it was used 10 kg higher weight of subject, and it was administered 212 mg of carboplatin instead of 189 mg	Key
	30APR2018 (155)	Laboratory	For subject 1148004 samples for Covance and BST laboratories were not collected on Post treatment visit. Patient came on C5D36, and afterwards was decided that this can be consider as PTV.	Non-Key
	26JUN2018 (212)	Laboratory	During PTV for subject 1148004, by omission of lab stuff value of calcium was not analysed.	Non-Key
1156002	07SEP2018 (219)	Dosing	Patient had second episode of neutropenia (AE#14). Gem was alredy reduced (due to first episode of thrombocitopenia) so site should reduce Carbo. This was not done.	Non-Key
1163001	22DEC2017 (37)	Laboratory	Site staff has ommitted to withdraw and send the samples for PBMC Whole Blood Samples to the central lab BST, during C1D1, performed on 16.Nov.2017	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1163001	22DEC2017 (37)	Visit/Procedure Required	Vital signs after trilaciclib/before Gem; and after Gem/before Carboplatin were not taken during C1D1, on 18.Nov.2017	Non-Key
	20JUL2018 (247)	Visit/Procedure Required	PD – TA for patient 001 was not done on 21Jun2018, 12 weeks from the 29.Mar.2018. It was done on 09Jul2018.	Non-Key
1163005	22FEB2018 (58)	Visit Schedule	Radionuclide Bone Scan for pt 1163-005 was performed on 28.Nov.2017, and randomization is performed on 27.Dec.2017, which is on 29th day. According to protocol should be within 28 days prior thedosing.	Non-Key
	03SEP2018 (251)	Laboratory	Haemato-toxicity from C7D15, for pt.1163005 was not followed on 30/May/2018, as patient did not attend D22, due to personal matters.	Non-Key
	06SEP2018 (254)	Laboratory	PD - hemotoxicities and non-hemotoxicities from C6D15 (AE#33, 34, 35) were not followed up within 1 week due to patients personal reasons. Patient came two weeks later and C7 was initiated.	Non-Key
	21SEP2018 (269)	Laboratory	PD - Thrombocytopenia from C10D15 (AE#49) for 1163005 was not followed up within 1 week due to patient personal reasons. Patient came two weeks later and C11 was initiated.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1163005	08APR2019 (468)	Visit Schedule	PD: PTV2+60 days performed out of the visit window for pt 1163005. It should be performed at latest 15Feb2019, but due to patient's absence it was performed on 19Feb2019.	Non-Key
	11APR2019 (471)	Visit Schedule	PD: PTV2+60 days performed out of the visit window for pt 1163005. It should be performed at latest 15Feb2019, but due to patient's absence it was performed on 19Feb2019.	Non-Key
1165001	24AUG2017 (79)	Concomitant Medications	Site administered short-acting G-CSF on 29-Jun-2017 within 24 hours of G1T28 infusion on Cycle 2 Day 1 on 30-Jun-2017. Per the protocol, short-acting G-CSF products should be stopped at least 48 hoursprior to Day G1T28 infusions for Groups 2 and 3.	Key
	20OCT2017 (136)	Visit/Procedure Required	Patient 1165-001 did not complete the FACT An & B questionnaire during Cycle 7 Day 1 (12-Oct-2017) visit. The patient had recently suffered a family tragedy and elected to not complete thequestionnaire.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1165001	12SEP2018 (463)	Concomitant Medications	The did not receive GCSF during cycle 3 or cycle 14 after a delay in C2D1 (30June2017) due to a Gr3 Neutropenia that occurred on 21June2017 (C1D15). The subject had previously received GCSF duringcycle 2 and should have continued at each cycle subsequent cycle.	Non-Key
	16JAN2019 (589)	Visit Schedule	The following Tumor Assessments for patient 1165-001 were done out of window: - Week 27 Tumor Assessment occurred on 29Dec2017 but should have occurred on 08Dec2017 - Week 51 Tumor Assessment occurredon 15Jun2018 but should have occurred on 28Jun2018	Non-Key
1166001	23MAR2018 (16)	Visit/Procedure Required	Patient has previous bone scan dated 22 Jan 2018, which is used for study purposes and it is not within the allowed window of 28 days prior first dose, which was on 08 Mar 2018. New bone scan had notbeen done after obtaining of informed consent in the interest of patient well-being. There are 17 days of delay.	Non-Key
	04MAY2018 (58)	Dosing	Dosing on C2D8 was skipped due to neutropenia ANC 1.24.	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1166001	04MAY2018 (58)	Dosing	Site should start with prophylactic GCSF in Cycle 2 as the first approach to managing the neutropenia, but site only administered G-CSF for treating neutropenia in Cycles 1,2 and 3, not asprophylactic.	Non-Key
	04MAY2018 (58)	Laboratory	Missing Albumin and Alkaline phosphatase results for C2D1	Non-Key
	04MAY2018 (58)	Laboratory	Missing Calcium result for C3D1.	Non-Key
	04MAY2018 (58)	Visit Schedule	C2D8 (05 Apr 2018) visit has been performed on day 7 after C2D1 (30 Mar 2018), instead of day 8. The patient lives far away from site and it is hard to organize transportation on certain days.	Non-Key
	04MAY2018 (58)	Visit Schedule	On 19 Apr 2018 patient received G-CSF (Filgrastim). On the next day, 20Mar2018 Cycle 3 started. Only 24h passed from G-CSF administartion and trilaciclibe administartion.	Key
	04MAY2018 (58)	Visit Schedule	Procedures for Cycle 2 Day 1 were performed on 29 Mar 2018 and 30 Mar 2018. C2D1 was scheduled on 29Mar, but due to technical issues IMP has not been dispensed. IMP has been dispensed on 30 Mar 2018and C2D1 has been continued that day.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1166001	05JUN2018 (90)	Visit Schedule	Follow-up MRI and CT have not been performed within 9 weeks from screening tumor assessment, on 24Apr ± 7 days. Scans were done 11 May 2018.	Non-Key
	23JUL2018 (138)	Laboratory	PD: Albumin has not been tested on Cycle 7 Day 1.	Non-Key
	23JUL2018 (138)	Laboratory	PD: BUN has not been tested on Cycle 6 Day 1. Update 05Sep: urea was not tested so site can not calculate BUN.	Non-Key
	23JUL2018 (138)	Laboratory	PD: BUN has not been tested on Cycle 6 Day 22. Update 05Sep: urea was not tested so site can not calculate BUN.	Non-Key
	12SEP2018 (189)	Laboratory	PD: Albumin was not tested on Cycle 8 Day 1.	Non-Key
	12SEP2018 (189)	Visit Schedule	PD: C8D8 has not been performed within the allowed time window as per protocol, it has been performed on 28 Aug 2018 instead of 22 Aug 2018. The reson for delay is patient's personal matter. No AE orany other medical occurens reson for delay. No on site visit between 15 and 28 Aug.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1D8 + GC Therapy D1D8				
1166001	09JAN2019 (308)	Non-compliance	Patient had PD from 14Aug2018 but this was not identified by Site personnel. Site compared target lesion diameter from Aug with the screening diameter, not the smallest one. Due to this omissionpatient remained on study until 12 Sep 18. Patient should have been removed from treatment at the time PD was identified.	Key
	19MAR2019 (377)	Dosing	Due to vacation patient could not come on site on 21Aug for C8D8 dosing. She came on 28Aug2018 and site performed activities for V8 instead of activities for V15. Protocol does not allow dose delayson Day 8 not dosing on D15.	Non-Key
	07MAY2019 (426)	Visit Schedule	C3D15 was not performed on 04May2018 or new cycle initiated. Due to AE patient was not treated on C3D8 on 27Apr2018. Patient only received Zarzio. PI decided that C3D15 should not be peformed and thatpatient will start with new cycle on 11May2018 although AE terminated 28Apr2018.	Non-Key
	08MAY2019 (427)	Visit/Procedure Required	Patient should have start C3D1 on 11Apr18 but didn’t even though lab results were OK.	Non-Key
	03JUN2019 (453)	Laboratory	On the visit dated 12 Sep 2018 BUN has not been tested	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1111002	05MAR2018 (83)	Visit/Procedure Required	Vitals not obtained immediately after infusion on Cycle 1 Day 1 (13DEC2017).	Non-Key
	05MAR2018 (83)	Visit/Procedure Required	Vitals not obtained immediately after infusion on Cycle 1 Day 8 (20DEC2017).	Non-Key
	05MAR2018 (83)	Visit/Procedure Required	Vitals not obtained immediately after infusion on Cycle 2 Day 1 (03JAN2018).	Non-Key
	27APR2018 (136)	Visit/Procedure Required	The site did not obtain a radionucleotide bone scan at the screening visit on 04-Dec-2017.	Key
	20JUL2018 (220)	Visit/Procedure Required	Post-Treatment Visit 2 (+60 days) Immunologic Markers in Blood not collected 21MAR2018.	Non-Key
1111004	07APR2018 (74)	Visit/Procedure Required	Subject 1111-004 C1D1 Post dose G1T28 Vitals was not assessed.	Non-Key
	07APR2018 (74)	Visit/Procedure Required	Subject 1111-004 C3D1 Post dose G1T28 vitals was not assessed on 21mar2018.	Non-Key
	04MAY2018 (101)	Laboratory	Cycle 3 Day 15 Safety Labs not completed on 04APR2018.	Non-Key
	29JUL2018 (187)	Visit Schedule	C8D8 and D9 were each conducted one day early (11July2018 and 12July2018). The subject's treatment schedule had been adjusted for C8D1 and D2 to accommodate the holiday on 04July2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1111004	19AUG2018 (208)	Concomitant Medications	On C3D9 (29mar2018), C4D9 (19Apr2018), C5D9 (10May2018), C6D9 (31May2018), C7D9 (21June2018) and C8D9 (12July2018) the patient was given Pegfilgrastim. Pegfilgrastim should only be given 24 -48 hoursafter D8/D9.	Key
	26AUG2018 (215)	Laboratory	The phosphorous was not done as part of the clinical chemistry labs on C7D1 on 13Jun2018.	Non-Key
	12DEC2018 (323)	Visit/Procedure Required	Post Treatment Visit 2 (+- 60 Days) on 26Sep18 â€“ Immunological (flow) and (PBMC) marker samples not done.	Non-Key
1112001	19APR2017 (72)	Enrollment Criteria	Radionucleotide Bone Scan was not completed during screening for Patient 1112-001. UPDATE 07-Sep-2017: Per review by G1 and INC Protocol Deviation Review team, this PD has been changed from Major toMinor. The EDC system has been updated and the site staff notified. This was changed to minor because the subject had a PET scan which has been recorded in the concomitant procedures page.	Non-Key
	18MAY2017 (101)	Visit/Procedure Required	Post-Gemcitabine vitals assessment was not completed during the Cycle 1 Day 9 visit (15-Feb-2017)	Non-Key
	18MAY2017 (101)	Visit/Procedure Required	Temperature not taken during the vitals assessment post-Gemcitabine infusion on Cycle 2 Day 1 (07-Mar-2017).	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1112001	11AUG2017 (186)	Visit/Procedure Required	Physical Exam was not performed during PTV 1 (06-Jun-2017).	Non-Key
	31OCT2017 (267)	Visit Schedule	PTV 2 Tumor Assessment performed 2 days outside of protocol-defined window.	Non-Key
	03APR2018 (421)	Laboratory	The LDH levels were not assessed as part of the clinical chemistry labs which were done as part of the screening visit on 02-Feb-2017 or C1D1 on 07Feb2018	Non-Key
	03APR2018 (421)	Laboratory	The site did not assess inorganic phosphorous as part of the clinical chemistry at any time during the subject's participation on the study (02-Feb-2017 to EOS on 06-June-2017)	Non-Key
	15JAN2019 (708)	Visit/Procedure Required	C1D1 (7 Feb 2017) PBMC and Flow samples not collected.	Non-Key
1112006	03APR2018 (232)	Non-compliance	Inorganic Phosphorous was not assessed in clinical chemistry labs at any visit during the subject's participation from screening on 08-Aug-2017 through PTV#1 on 10-Oct-2017.	Key
	10SEP2018 (392)	Enrollment Criteria	The subject was screened and enrolled under protocol version 3 amendment 2. The subject was screened on 08Aug2017. The subject did not have measurable lesions per RECIST 1.1. The site included bonelesions as measurable lesions.	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1113005	12FEB2018 (41)	Visit/Procedure Required	Cycle 1 Day 8 (10Jan2018) post-G1T28-04 vital signs were not assessed. Pre-treatment vitals were collected.	Non-Key
	25APR2018 (113)	Visit/Procedure Required	Cycle 5 Day 8 (04-Apr-2018) post-G1T28 infusion vital sign assessment was not completed.	Non-Key
	30MAY2018 (148)	Visit/Procedure Required	Cycle 7 Day 1 (09-May-2018) temperature not recorded for post-G1T28 infusion vital sign assessment.	Non-Key
	16JUL2018 (195)	Visit/Procedure Required	Cycle 8 Day 8 (06-Jun-2018) post-G1T28 infusion vital sign assessment was not completed.	Non-Key
	16JUL2018 (195)	Visit/Procedure Required	Respiratory Rate was not recorded for Cycle 8 Day 9 (07-Jun-2018) post-G1T28 infusion vital signs assessment.	Non-Key
	13AUG2018 (223)	Visit/Procedure Required	Cycle 11 Day 1 (01-Aug-2018) post-G1T28 infusion vital sign assessment was not completed.	Non-Key
	13SEP2018 (254)	Visit/Procedure Required	Cycle 12 Day 8 (29-Aug-2018) post-G1T28 infusion vital sign assessment was not completed.	Non-Key
	03DEC2018 (335)	Visit/Procedure Required	Cycle 14 Day 8 (17-Oct-2018) post-G1T28 infusion vital signs assessment was not completed.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1113005	20MAY2019 (503)	Visit Schedule	Post Treatment Visit 1 visit completed out of Window. Site has this visit recorded as 09Jan19 but some assessments were also completed 16Jan19.	Non-Key
	20MAY2019 (503)	Visit Schedule	Post Treatment Visit 2 completed out of window. PTV2 due 60 days +/- 7 days after Post Treatment Visit 1	Non-Key
1116001	08NOV2017 (10)	Visit Schedule	The CBC for Cycle 1 Day 1 was drawn greater than 24 hours of the patient dosing.	Key
	08NOV2017 (10)	Visit/Procedure Required	The Immunologic Markers in Blood - Cycle 1 Day 1 were not drawn.	Non-Key
	08NOV2017 (10)	Visit/Procedure Required	The vital signs for cycle 1 day 2 Post-dose G1T28/Pre-dose Carboplatin & Post-dose Carboplatin/ Pre-dose Gemcitabine were not completed	Non-Key
	04APR2018 (157)	Laboratory	Cycle 8 Day 1 Clinical Chemistry not drawn on 19MAR2018.	Non-Key
	04APR2018 (157)	Visit/Procedure Required	Cycle 8 Day 1 FACT-B and FACT-An questionnaires not completed on 19MAR2018.	Non-Key
	06SEP2018 (312)	Concomitant Medications	Cycle 7 Day 8/9 skipped on 12MAR2018 due to neutropenia, but G-CSF was not added to subsequent cycles (Cycle 8 19MAR2018) per protocol.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1116001	06SEP2018 (312)	Visit Schedule	Post Treatment Visit 2 (17JUL2018) out of window. Per G1T28-04 Protocol Am 3 Clarification #2 on 26APR18, PVT2 is intended to capture 90 days after last dose of treatment (15MAY2018).	Non-Key
	06SEP2018 (312)	Visit/Procedure Required	Immunologic Markers in Blood Post-Treatment Visit 2 (+60 days) not collected on 17JUL2018.	Non-Key
1116003	22FEB2018 (25)	Visit/Procedure Required	Post dose Carboplatin/ Predose Gemcitabine Vitalsnot taken on C1D2 (30JAN18), C1D9 (06FEB2018) and C2D2 (20FEB2018).	Non-Key
	02MAR2018 (33)	Visit Schedule	Screening Radionuclide Bone Scan (29DEC2017) not performed within 28 days prior to the first dose of study drug (29JAN2018). The scan was done 1 day out of window.	Non-Key
1117002	07SEP2018 (233)	Concomitant Medications	Growth factor (Pegfilgrastim) administered within 24-hours of Cycle 8 Day 2 (28-Jun-2018) infusions.	Key
	12SEP2018 (238)	Visit Schedule	Visit C2D1 was performed on 07Feb2018 which was 20 days after Cycle1 Day1 on 18Jan2018. Visit C7D1 was performed on 12June2018 which was 20 days after C6D1 on 23May2018. These visits are one dayshorter than required by protocol.	Non-Key
	12SEP2018 (238)	Visit/Procedure Required	Post dose Carboplatin/ Predose Gemcitabine vitals sings were not taken at C3D2 on 01-Mar-2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1117002	17DEC2018 (334)	Visit/Procedure Required	Cycle 14 Day 2 (24-Oct-2018) Respiratory Rate and Temperature were not completed for all four vital sign time points.	Non-Key
	21JAN2019 (369)	Visit/Procedure Required	Cycle 15 Day 1 (13Nov2018) PBMC and FLOW immunological laboratory samples were not collected.	Non-Key
	02JUL2019 (531)	Visit/Procedure Required	ECOG was not done at Post Treatment Visit 1 (05Apr2019).	Non-Key
	15JUL2019 (544)	Laboratory	Chemistries Albumin, Alkaline phosphatase, Total bilirubin, Inorganic phosphorus, Total protein, ALT, AST, LDH were not done at Post Treatment Visit 1 (05Apr2019). In addition, Hematology'sEosinophils (absolute), Basophils (absolute), Eosinophils (percentage), Basophils (percentage) were also not done at Post Treatment Visit 1.	Non-Key
	08APR2020 (812)	Visit/Procedure Required	PMBC and FLOW Samples not done at Post Treatment Visit 1 on 05Apr2019.	Non-Key
1117006	09MAY2018 (23)	Visit/Procedure Required	Cycle 1 Day 2 (18Apr2018) PK sample collection was completed using the incorrect laboratory manual. The outdated manual used (v1.0 31Jan2017) does not contain the updated time points reflected in thecurrent lab manual (v3.0 11Dec2017).	Non-Key
	19OCT2018 (186)	Visit/Procedure Required	Cycle 7 Day 15 projected for 13-15Aug2018 was not conducted.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1117006	17DEC2018 (245)	Laboratory	Cycle 8 Day 1 (11-Sep-2018) LDH was not completed on the Complete Metabolic panel.	Non-Key
	17DEC2018 (245)	Visit/Procedure Required	Cycle 10 Day 2 (24-Oct-2018) Respiratory Rate was not recorded for all four vital sign time points.	Non-Key
	17DEC2018 (245)	Visit/Procedure Required	Cycle 10 Day 2 (24-Oct-2018) temperature was not recorded for pre-G1T28 infusion vital signs.	Non-Key
	17DEC2018 (245)	Visit/Procedure Required	Cycle 6 Day 15 (projected 15-Aug-2018) was not completed.	Non-Key
	17DEC2018 (245)	Visit/Procedure Required	Cycle 7 Day 1 (21-Aug-2018) PBMC and FLOW laboratory samples were not collected.	Non-Key
	30APR2019 (379)	Visit/Procedure Required	Post Treatment Visit 2 (60 days post last dose - 23Jan2019) - Immunologic Markers in Blood - Post-Treatment Visit 2 (+60 days) were not collected.	Non-Key
	05JUN2019 (415)	Concomitant Medications	G-CSF given only for 1 dose and not continued after the remaining chemotherapy cycles as per table 8-1 in the protocol.	Non-Key
1118001	31JUL2017 (61)	Visit/Procedure Required	Due to an error by the study coordinator, the Immunologic PBMC laboratory sample was not collected for patient 1118-001 during the Post Treatment Visit (10Jul2017).	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1118001	31JUL2017 (61)	Visit/Procedure Required	Immunologic PBMC laboratory sample was not collected for patient 1118-001 during the Cycle 1 Day 1 visit (01Jun2017). Lab kits were available to the site at this time. This was an error by the site.	Non-Key
	31JUL2017 (61)	Visit/Procedure Required	Patient 1118-001 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 1 Day 2 visit (02Jun2017).	Non-Key
	09OCT2017 (131)	Visit/Procedure Required	Patient 1118-001 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 2 Day 9 visit (29Jun2017).	Non-Key
	09OCT2017 (131)	Visit/Procedure Required	Post-G1T28 infusions vital assessment not completed for patient 1118-001 C1D1 visit (13-Jul-2017).	Non-Key
	10OCT2017 (132)	Visit/Procedure Required	Patient 1118-001 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 1 Day 9 visit (09Jun2017).	Non-Key
	10OCT2017 (132)	Visit/Procedure Required	Patient 1118-001 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 2 Day 2 visit (22Jun2017).	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1118001	14NOV2017 (167)	Visit Schedule	Patient 1118-001 Post Treatment Visit 1 conducted out of window on 10Jul2017. Based on the protocol and patient visit schedule, the PTV 1 should have occurred between 12-19Jul2017. Visit was 2 daysout of window	Non-Key
	19DEC2017 (202)	Visit Schedule	Cycle 1 Day 15 (13-Jun-2017) visit conducted out of window. Per the protocol, the Day 15 visit should have been conducted on 15-Jun-2017 (+/- 1-day).	Non-Key
	08MAR2018 (281)	Non-compliance	There are multiple and repetitive instances of protocol non-compliance. The site has missed protocol required vital sign collection during multiple study visits. There have been at least 2 instancesof missed lab sample collection. There have instances of out of window visit procedures	Key
	26JUN2018 (391)	Visit Schedule	C1D15 was conducted 2 days out of window. The visit should have been done on 15June2018 but it occurred on 13June2017	Non-Key
1118002	31JUL2017 (19)	Visit/Procedure Required	Due to an error by the study coordinator, Immunologic PBMC and FLOW laboratory samples were not collected for patient 1118-002 during the Cycle 1 Day 1 visit (13Jul2017).	Non-Key
	31JUL2017 (19)	Visit/Procedure Required	Patient 1118-002 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 1 Day 2 visit (14Jul2017).	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1118002	09OCT2017 (89)	Visit Schedule	Cycle 3 Day 1 (24Aug2017) Immunologic Lab samples (PBMC and FLOW) were collected out of window (22Aug2017) for patient 1118-002.	Non-Key
	09OCT2017 (89)	Visit Schedule	Patient 1118-002 Cycle 1 Day 1 (13Jul2017) ECOG was performed out of window on 11Jul2017.	Non-Key
	09OCT2017 (89)	Visit Schedule	Patient 1118-002 Screening Radionucleotide Bone Scan and CT Scan completed outside of the protocol-defined 28-day screening window.	Non-Key
	10OCT2017 (90)	Visit Schedule	Patient 1118-002 Cycle 2 Day 1 (03Aug2017) ECOG and Physical Exam were performed out of window on 01Aug2017.	Non-Key
	10OCT2017 (90)	Visit Schedule	Patient 1118-002 Cycle 3 Day 1 (24Aug2017) ECOG and Physical Exam were performed out of window on 22Aug2017.	Non-Key
	10OCT2017 (90)	Visit Schedule	Patient 1118-002 Cycle 4 Day 1 (14Sep2017) ECOG and Physical Exam were performed out of window on 12Sep2017.	Non-Key
	10OCT2017 (90)	Visit/Procedure Required	Patient 1118-002 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 1 Day 9 visit (21Jul2017).	Non-Key
	10OCT2017 (90)	Visit/Procedure Required	Patient 1118-002 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 2 Day 2 visit (04Aug2017).	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1118002	10OCT2017 (90)	Visit/Procedure Required	Patient 1118-002 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 2 Day 9 visit (11Aug2017).	Non-Key
	10OCT2017 (90)	Visit/Procedure Required	Patient 1118-002 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 3 Day 2 visit (25Aug2017).	Non-Key
	10OCT2017 (90)	Visit/Procedure Required	Patient 1118-002 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 3 Day 9 visit (01Sep2017).	Non-Key
	10OCT2017 (90)	Visit/Procedure Required	Patient 1118-002 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 4 Day 2 visit (15Sep2017).	Non-Key
	10OCT2017 (90)	Visit/Procedure Required	Patient 1118-002 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 4 Day 9 visit (22Sep2017).	Non-Key
	07NOV2017 (118)	Visit/Procedure Required	Post-G1T28 vital signs were not recorded during Cycle 1 Day 1 visit (13Jul2017).	Non-Key
	15NOV2017 (126)	Visit Schedule	Patient 1118-002 Cycle 5 Day 1 (05Oct2017) Physical Exam was performed out of window on 03Oct2017.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1118002	19DEC2017 (160)	Visit Schedule	Cycle 3 Day 15 (05-Sep-2017) conducted out of window. Based on protocol and patient visit schedule, Cycle 3 Day 15 should have been conducted on 07-Sep-2017 (+/- 1 day).	Non-Key
	19DEC2017 (160)	Visit Schedule	Cycle 4 Day 15 (26-Sep-2017) conducted out of window. Based on protocol and patient visit schedule, Cycle 4 Day 15 should have been conducted on 28-Sep-2017 (+/- 1 day).	Non-Key
	19DEC2017 (160)	Visit Schedule	Cycle 5 Day 15 (17-Oct-2017) conducted out of window. Based on protocol and patient visit schedule, Cycle 5 Day 15 should have been conducted on 19-Oct-2017 (+/- 1 day).	Non-Key
	19DEC2017 (160)	Visit Schedule	Cycle 6 Day 15 (07-Nov-2017) conducted out of window. Based on protocol and patient visit schedule, Cycle 6 Day 15 should have been conducted on 09-Nov-2017 (+/- 1 day).	Non-Key
	19DEC2017 (160)	Visit/Procedure Required	Cycle 8 Day 2 (01-Dec-2017) post-G1T28/pre-Gemcitabine, post-Gemcitabine/pre-Carboplatin, and post-Carboplatin vitals assessments were not completed.	Non-Key
	08JAN2018 (180)	Visit Schedule	Cycle 7 Day 8 & 9 (23-24Nov2017) skipped due administrative reasons (Thanksgiving Holiday). The protocol does not permitted stud dosing to be skipped for administrative reasons.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1118002	28FEB2018 (231)	Visit/Procedure Required	Cycle 10 Day 2 (02-Feb-2018) post-Carboplatin vital signs were note recorded.	Non-Key
	08MAR2018 (239)	Non-compliance	The site has been non-compliant with several aspects of the study protocol. There are have been multiple incidents of missed vital signs and other study procedures. There have also been visitprocedures including physical exams and ECOGs conducted out of window. Multiple lab sample collections have been missed.	Key
	28MAR2018 (259)	Visit Schedule	Site collected both Immunologic and PBMC samples on 03-Oct-2017 which is two days out of window for the C5D1 visit on 05-Oct-2017	Non-Key
	17APR2018 (279)	Visit/Procedure Required	The site did not collect the PBMC samples at C7D1 (16Nov2018).	Non-Key
	07MAY2018 (299)	Laboratory	Cycle 10 Day 1 (01-Feb-2018) hematology lab assessment did not report the Absolute Neutrophil Count (ANC) required for Day 1 dosing clearance. The Neutrophil percentage was also not captured.	Key
	07MAY2018 (299)	Visit/Procedure Required	Cycle 12 Day 15 (projected 29-31 Mar 2018) was not conducted.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1118002	29JUN2018 (352)	Laboratory	Cycle 14 Day 1 (17May2018) 5-part differential with Granulocytes reported 17May2018, but absolute neutrophil count (ANC) was reported out of window on 15May2018.	Key
	29JUN2018 (352)	Visit/Procedure Required	Cycle 14 Day 1 (17May2018) complete metabolic panel did not provide a result for Phosphorus.	Non-Key
	29JUN2018 (352)	Visit/Procedure Required	Cycle 14 Day 2 (18May2018) post-Carboplatin vital signs assessment were not completed.	Non-Key
	29JUN2018 (352)	Visit/Procedure Required	Cycle 14 Day 2 (18May2018) post-Gemcitabine/pre-Carboplatin vital signs assessment were not completed.	Non-Key
	08AUG2018 (392)	Visit Schedule	The subject's hematology labs were completed on 15May2018 which is more than 24 hours before the C14D1 visit on 17May2018	Key
1118003	09OCT2017 (20)	Visit Schedule	Patient 1118-003 Cycle 1 Day 1 (20Sep2017) Immunologic PBMC sample taken out of window on 22Sep2017.	Non-Key
	09OCT2017 (20)	Visit/Procedure Required	Patient 1118-003 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 1 Day 2 visit (21Sep2017).	Non-Key
	08NOV2017 (50)	Visit/Procedure Required	Patient 1118-003 post-Gemcitabine/pre-Carboplatin vital signs were not recorded during Cycle 1 Day 9 visit (28Sep2017)	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1118003	14NOV2017 (56)	Visit Schedule	Patient 1118-003 Cycle 2 Day 1 (25Oct2017) ECOG and Physical Exam were performed out of window on 24Oct2017.	Non-Key
	23FEB2018 (157)	Visit Schedule	Post-Treatment Visit (26-Dec-2017) FACT An & B questionnaire completed out of window on 28-Dec-2017.	Non-Key
	23FEB2018 (157)	Visit Schedule	Post-Treatment Visit (26-Dec-2017) Immunologic PBMC sample collected out of window on 28-Dec-2017.	Non-Key
	23FEB2018 (157)	Visit/Procedure Required	Post-Treatment Visit (26-Dec-2017) Immunologic FLOW sample was not collected.	Non-Key
	23FEB2018 (157)	Visit/Procedure Required	Post-Treatment Visit 2 (22-Jan-2018) Immunologic FLOW sample was not collected.	Non-Key
	23FEB2018 (157)	Visit/Procedure Required	Post-Treatment Visit 2 (22-Jan-2018) Immunologic PBMC sample was not collected.	Non-Key
	08MAR2018 (170)	Non-compliance	There have been multiple instances of protocol non-compliance. There have been multiple instances of missed lab sample collection. There have been instances of missed vital sign collection and visitprocedures conducted out of window.	Key
	22MAY2018 (245)	Laboratory	A urinalysis sample was not collected or run at PTV #1 (26-Dec-2018).	Non-Key
1118005	27JUN2018 (183)	Visit Schedule	Cycle 5 Day 15 (03-Apr-2018) was projected for 04-06 Apr 2018, but was conducted out of window on 03-Apr-2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1118005	27JUN2018 (183)	Visit Schedule	Cycle 5 Day 8 (28-Mar-2018) was projected for 29-Mar-2018, but was conducted out of window on 28-Mar-2018.	Non-Key
	27JUN2018 (183)	Visit Schedule	Cycle 7 Day 1 (09-May-2018) Hematology lab completed out of window on 07-May-2018.	Key
	07AUG2018 (224)	Visit Schedule	Cycle 8 Day 1 (05-Jun-2018) ECOG performance assessment completed out of window on 04-Jun-2018.	Non-Key
	07AUG2018 (224)	Visit Schedule	Cycle 8 Day 1 (05-Jun-2018) Hematology lab completed out of window on 04-Jun-2018.	Non-Key
	07AUG2018 (224)	Visit Schedule	Cycle 8 Day 1 (05-Jun-2018) physical exam completed out of window on 04-Jun-2018.	Non-Key
	07AUG2018 (224)	Visit/Procedure Required	Cycle 3 Day 1 (07-Feb-2018) immunology FLOW sample was not collected.	Non-Key
	07AUG2018 (224)	Visit/Procedure Required	Cycle 5 Day 1 (22-Mar-2018) immunology FLOW sample was not collected.	Non-Key
	07AUG2018 (224)	Visit/Procedure Required	Cycle 5 Day 1 (22-Mar-2018) immunology PBMC sample was not collected.	Non-Key
	07AUG2018 (224)	Visit/Procedure Required	Cycle 5 Day 8 (28-Mar-2018) post-G1T28 infusion vital signs were not recorded.	Non-Key
	07AUG2018 (224)	Visit/Procedure Required	Cycle 5 Day 9 (29-Mar-2018) infusion vital signs were not recorded at all four protocol-required time-points.	Non-Key
	07AUG2018 (224)	Visit/Procedure Required	Cycle 7 Day 1 (09-May-2018) physical exam completed out of window on 07-May-2018.	Non-Key
1120001	04JUL2017 (114)	Laboratory	The protocol required immunologic markers missed for C1D1 on 13March2017	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1120001	17APR2018 (401)	Laboratory	Post-Treatment Visit 1 Urinalysis not completed on 12JUN2017.	Non-Key
	01JUN2018 (446)	Visit/Procedure Required	Cycle 3 Day 2 Predose G1T28 body temperature not assessed on 25APR2018.	Non-Key
1120002	13FEB2018 (6)	Visit/Procedure Required	Subject 1120-002 C1D1 immunological (PBMC) marker missed on 08Feb2018.	Non-Key
	23MAR2018 (44)	Laboratory	Subject 1120-002 inorganic phosphorous and LDH chemistry test not completed on Cycle 2 Day 1 (08MAR2018).	Non-Key
	23MAR2018 (44)	Visit/Procedure Required	Subject 1120-001 Physical examination not performed Cycle 2 Day 1 (08MAR2018).	Non-Key
	17APR2018 (69)	Laboratory	inorganic phosphorous chemistry test not completed on Cycle 3 Day 1 (22MAR2018).	Non-Key
	27APR2018 (79)	Laboratory	Subject 1120-002 inorganic phosphorous and LDH chemistry test not completed on Cycle 4 Day 1 (16APRR2018).	Non-Key
	27APR2018 (79)	Visit/Procedure Required	Post dose G1T28 vitals not assessed on Cycle 3 Day 1 (22MAR2018).	Non-Key
	30MAY2018 (112)	Visit/Procedure Required	ECOG was not assessed on C2D1	Non-Key
	01JUN2018 (114)	Visit/Procedure Required	Cycle 4 Day 1 Performance Status (ECOG) not assessed on 16APR2018.	Non-Key
	01JUN2018 (114)	Visit/Procedure Required	Cycle 4 Day 1 Physical Exam not performed on 16APR2018.	Non-Key
1122002	19DEC2017 (49)	Visit/Procedure Required	C2 D2 (16Nov2017) and C2 D9 (22Nov2018) vital signs not taken between carbo and gem.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1122002	15FEB2018 (107)	Visit/Procedure Required	C1D2 (02Nov2017) and D9(09Nov2017) vital signs not taken between Carboplatin and Gemcitabine dosing	Non-Key
	09MAY2018 (190)	Concomitant Medications	The site did not start the subject on GCSF after the first low ANC on 12Dec2017 on C1D8. This was an investigator decision. GCSF should have been started at cycle 2 and each subsequent cycle but hasnot been used at any cycle through cycle 9. The subject came off treatment after cycle 9 day 29 on 10May2018.	Non-Key
	15MAY2018 (196)	Visit/Procedure Required	The pt. refused to complete the QOL at the cycle 8 day 1 visit. (22Mar2018)	Non-Key
	28AUG2018 (301)	Dosing	The subject had an 11% weight change at C4D1 on 26Dec2017 but the site did not recalculate the dose of Gemcitabine using an updated BSA.	Non-Key
	05SEP2018 (309)	Visit/Procedure Required	At the PTV dated 10 May 2018 the UA and 12 lead EKG were not done	Non-Key
	15JAN2019 (441)	Visit/Procedure Required	Post treatment visit +60 immunological flow and PBMC Marker were not drawn on 19 July 2018	Non-Key
1122003				

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1125002	17FEB2018 (145)	Visit Schedule	The site held the cycle 2 day 8 dose for 1 week at and the following week treatment date did not move to the next cycle but continued with the current cycle day 8 visit.	Non-Key
	28MAR2018 (184)	Visit Schedule	The site collected PTV (22Jan2018) PBMC 7 days out of window on 29-Jan-2018.	Non-Key
	28MAR2018 (184)	Visit/Procedure Required	PBMC samples were not collected at C1D1 on 26-Sep-2017	Non-Key
	28MAR2018 (184)	Visit/Procedure Required	The site did not collect PBMC samples for C5D1 on 02Jan2018	Non-Key
	28MAR2018 (184)	Visit/Procedure Required	The site did not collect the PBMC samples at C3D1 on 13-Nov-2018.	Non-Key
	17APR2018 (204)	Visit/Procedure Required	The immunologic flow samples were not collected for the PTV#1 visit on 29Jan2018.	Non-Key
	25APR2018 (212)	Laboratory	The Hematology panel did not contain Basophil and Eosinophils at the following visits: Post-Treatment Visit 1, Cycle 1 Day 1, Cycle 2 Day 1, Day 8, Cycle 3 Day 1, Day 8, Cycle 3 Day 1, Day 8, Day 15,Cycle 4 Day 1, Day 8, Day 15, Cycle 5 Day 1, Day 8, Day 15.	Non-Key
	29AUG2018 (338)	Concomitant Medications	The subject was not given GCSF at the next cycle after a Gr3 Neutropenia on 24May2018 which should have ben C2D8. The subject should have received GCSF at all subsequent cycles.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1125003	17FEB2018 (143)	Visit/Procedure Required	The Central lab specimen for PBMC Immunological marker was not collected at cycle 7 day 1 on 01-Feb-2018	Non-Key
	17FEB2018 (143)	Visit/Procedure Required	The site did not collect the immunological (PBMC) marker for Clinical Logistics at Cycle 5 Day 1 on 21-Dec-2017.	Non-Key
	28MAR2018 (182)	Visit/Procedure Required	C1D1 (28-Sept-2017) PBMC sample was not collected.	Non-Key
	28MAR2018 (182)	Visit/Procedure Required	C3D1 (09-Nov-2017) PBMC sample was not collected	Non-Key
	28MAR2018 (182)	Visit/Procedure Required	C5D1 (21Dec2017) PBMC sample not collected.	Non-Key
	05APR2018 (190)	Visit/Procedure Required	Site did not collect blood sample for immunological (PBMC) marker for C9D1 on 15Mar18	Non-Key
	05APR2018 (190)	Visit/Procedure Required	Site did not complete FACT-An questionnaire on C7D1 01Feb18.	Non-Key
	29APR2018 (214)	Visit Schedule	The tumor assessments are due every 9 weeks (+/-7 days) prior to 27 weeks of study participation. The tumor assessment completed on 26 Jan 2018 which is 12 days out of window. The previous tumorassessment was done 05Nov2017 which was approximately 12 weeks earlier. Tumor assessments are done at 12 week intervals after 27 weeks of participation.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1125003	03MAY2018 (218)	Dosing	IP dosing error-The pharmacy technician on duty who had a prepared worksheet that stated the IP concentration of 10mg/mL, along with detailed step by step instructions on how to prepare the drug. Thedose in IKM was 382 mg which should have been 38.2 ml, the technician mistakenly entered 60 ml for the volume and printed on 60 ml on the label and put 60 ml in the bag which is 600 mg of IP insteadof the correct 382mg dose.	Key
	14OCT2019 (747)	Laboratory	Complete Metabolic Panel was not completed at the Cycle 5 Day 1 visit.	Key
	14OCT2019 (747)	Laboratory	Phosphorus was not reported along with CMP at the Day 1 visits for Cycles 2, 4 and 8.	Non-Key
	14OCT2019 (747)	Laboratory	Phosphorus was not reported along with CMP at the Screening visit.	Non-Key
	14OCT2019 (747)	Non-compliance	Pre-dose G1T28, post-dose G1T28/pre-Gemcitabine, post-Gemcitabine/pre-Carboplatin, and post-Carboplatin infusion vital sign assessments were not completed at multiple visits.	Key
	14OCT2019 (747)	Visit Schedule	Tumor Assessment #1 projected for 24-Nov-2017 (+/- 7 days) was completed out of window on 05-Nov-2017.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1125005	16JAN2019 (337)	Visit/Procedure Required	PTV+60 was not conducted	Non-Key
1126002	17APR2018 (335)	Visit/Procedure Required	Immunological markers were not collected at PTV#2 (28July2017)	Non-Key
	16JAN2019 (609)	Visit/Procedure Required	PTV (15 Jun 17) PBMC sample not collected.	Non-Key
1128002	05DEC2018 (267)	Visit/Procedure Required	For Subject 1128-002 Post Treatment Visit 2 (+- 60 Days) on 12Sep18, Immunological (flow) samples were not done.	Non-Key
	08AUG2019 (513)	Visit Schedule	Safety Follow-Up Phone call done out of 30 day (+/- 3 day) window.	Non-Key
1130001	01FEB2018 (94)	Visit/Procedure Required	C3D1 Immunological Marker (Flow) missed. (Sample collected, but shipped with wrong label.)	Non-Key
	04MAY2018 (186)	Visit Schedule	Cycle 7 Day 1 blood samples collected for immunological (flow) marker was collected out of window on 20Mar2018. The sample was not collected within 24 hours of dosing. It should have been collected on27MAR2018.	Non-Key
	04MAY2018 (186)	Visit/Procedure Required	Cycle 6 Day 8 Post dose G1T28 vitals missed on 06MAR2018.	Non-Key
	04MAY2018 (186)	Visit/Procedure Required	Cycle 7 Day 1 Post dose G1T28 Vitals missed on 27MAR2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1130001	11SEP2018 (316)	Dosing	Dose held Cycle 4 Day 8 on 11JAN2018 due to Subject 1130-001 Grade 3 neutropenia. The patient was eligible to resume treatment on 23JAN2018, but the site considered this Cycle 4 Day 15 and the patientdid not start Cycle 5 Day 1 until 30JAN2018.	Non-Key
1131004	30OCT2017 (103)	Laboratory	The site staff did not draw the required chemistry safety lab prior to dosing the patient with carboplatin at cycle 4 Day 1 12Oct2017.	Key
	09NOV2017 (113)	Visit/Procedure Required	The vital signs were not completed for Post-dose Carboplatin/pre-dose Gemcitabine and post-dose Gemcitabine at cycle 4 day 2.	Non-Key
	03APR2018 (258)	Laboratory	Phosphorous was not done during the clinical chemistry labs for the screening visit on 06-July-2017	Non-Key
	03APR2018 (258)	Laboratory	The Phosphorous was not done during the clinical chemistry labs for C2D22, C3D22 and C5D1. The lab used by the site for that visit does not run Phosphorous as a standard part of their chemistry.	Non-Key
	03APR2018 (258)	Laboratory	The site did not do complete chemistry for C5D1 (09Nov2017). The following analytes were not done: ALT, Alkaline Phosphatase, LDH, Total Bilirubin, AST, Phosphate(Phosphorous) AlbuminND Total Protein	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1131004	24JUL2018 (370)	Laboratory	The site staff did not draw the Clinical Chemistry - Cycle 4 day 22 (02-Nov-2017) for Pt. 1131-004.	Non-Key
	13JUN2019 (694)	Visit Schedule	Immunologic Markers in Blood collected 2 Nov 2018 and C5D1 was conducted 09 Nov 18. Labs were collected greater than 24 hours prior to the visit.	Non-Key
	07AUG2019 (749)	Visit/Procedure Required	Vital signs were not taken between Carboplatin/Gemcitabine and post Gemcitabine infusions on Day 2 and Day 9 at any applicable dosing visits in cycle 1 (except day 9), cycle 2, cycle 3, cycle 4, andcycle 5.	Non-Key
	22SEP2019 (795)	Visit Schedule	Time of vital signs was not documented in the EMR for pre and/ or post treatment infusions at C4D1, C4D9, and C5D8.	Non-Key
	13NOV2019 (847)	Laboratory	LDH was not collected at C2D22 on on 07SEP2017.	Non-Key
1131010	01MAR2018 (102)	Laboratory	Cycle 2 Day 1 (18Dec2017) Clinical Chemistry labs were collected 12 days out of window on 06Dec2017.	Key
	01MAR2018 (102)	Visit Schedule	Cycle 2 Day 15 (05Jan2018) visit performed out of window. Day 15 visit projected for 03Jan2018 (+/- 1-day).	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1131010	01MAR2018 (102)	Visit/Procedure Required	Cycle 3 Day 9 (16Jan2018) temperature and respiratory rate were not recorded for post-Gemcitabine/pre-Carboplatin infusion vital sign assessment.	Non-Key
	01MAR2018 (102)	Visit/Procedure Required	Cycle 4 Day 1 (29Jan2018) FACT An & B questionnaires were not completed. Source indicated patient refused to complete protocol-required assessment.	Non-Key
	01MAR2018 (102)	Visit/Procedure Required	Cycle 4 Day 1 (29Jan2018) pre-G1T28 and post-G1T28/pre-Gemcitabine infusion vital sign assessment was not performed.	Non-Key
	01MAR2018 (102)	Visit/Procedure Required	Cycle 4 Day 8 (05Feb2018) respiratory rate not recorded for post-G1T28 infusion vital sign assessment.	Non-Key
	01MAR2018 (102)	Visit/Procedure Required	Cycle 5 Day 2 (20Feb2018) post-Carboplatin infusion vital sign assessment time was not recorded.	Non-Key
	03APR2018 (135)	Laboratory	Phosphate was not as part of the Chemistry labs on C1D1 (20Nov2017). Phosphate is not part of their standard set of analytes performed with the chemistry at the labs used for this visit.	Non-Key
	25APR2018 (157)	Visit/Procedure Required	Cycle 8 Day 1 (23-Apr-2018),Cycle 8 Day 2 (24-Apr-2018), Cycle 8 Day 2 (24-Apr-2018), and Cycle 8 Day 2 (24-Apr-2018) time of post-G1T28 vital sign assessment was not recorded.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1131010	28APR2018 (160)	Visit Schedule	The tumor assessment was conducted 12 days out of window. It was completed on 22Jan2018. It was due on 03Jan2018 (+/- 7 days)	Non-Key
	18JUL2018 (241)	Visit/Procedure Required	Cycle 9 day 1 (14-May-18)- Vital Signs were not collected for Post dose Carboplatin/ Predose Gemcitabine and Post dose Gemcitabine	Non-Key
1145003	12JUN2018 (72)	Visit Schedule	Screening Brain Scan (19FEB2018) not completed with 28 days of dosing (02APR2018).	Non-Key
	13JUN2018 (73)	Visit/Procedure Required	Immunologic Markers in Blood not collected for Cycle 1 day 1 on 02APR2018.	Non-Key
	16JUL2018 (106)	Visit Schedule	Hematology (21MAY2018) obtained more than 24 hours prior to dosing on Cycle 3 Day 8 (23MAY2018).	Key
	16JUL2018 (106)	Visit/Procedure Required	Post dose G1T28 vitals not collected C2D8 on 03MAY2018.	Non-Key
	16JUL2018 (106)	Visit/Procedure Required	Predose G1T28 respiratory rate not assessed on C2D8 on 03MAY2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1145003	17JUL2018 (107)	Dosing	Cycle 5 Day 1 was delayed due to low platelets on 05JUL2018. The subject resumed treatment on 12JUL2018, but no dose modifications were taken for Carbo on 13JUL2018. Per protocol, for the secondepisode of low platelets hold drug until platelet criteria for dosing is reached; Gemcitabine is held at 800 mg/m2 and Carboplatin reduce to AUC 1.5.	Non-Key
	17JUL2018 (107)	Laboratory	Clinical Chemistry labs not drawn Cycle 3 Day 1 on 16MAY018.	Non-Key
	17JUL2018 (107)	Regulatory	Subject 1145-003 was admitted to the hospital from ER on 27JUN2018 for chest pain, site failed to report safety information within 24 hours of discovery (11JUL2018).	Key
	17JUL2018 (107)	Visit/Procedure Required	Cycle 5 Day 1 PBMC lab kit missed on 12JUL2018.	Non-Key
	25JUL2018 (115)	Concomitant Medications	Subject experienced Low ANC at C3D8 (23MAY2018). Dose was correctly skipped, but GCSF not added to subsequent visits starting with Cycle 4.	Non-Key
	25JUL2018 (115)	Concomitant Medications	Subject had Low ANC at C3D8 on 23MAY2018. Dose was correctly skipped, but GCSF not added to subsequent visits starting with Cycle 4 On 14JUN2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1145003	25JUL2018 (115)	Dosing	C4D2 on 14JUN2018 Site should have reduced Gemcitabine to 800 due to low platelet at C3D1(16MAY2018).	Non-Key
	25JUL2018 (115)	Dosing	On 16MAY2018 C3D1 Subject 1145-003 platelets were 77, site shouldn't have dosed at Day 2. Per protocol, Patients must meet Platelet count >=100 x 10**9/L criteria to receive the Day 1/2 dose.	Key
	25JUL2018 (115)	Visit Schedule	C3D1 (16MAY2018) visit out of window,should have occurred one day later on 17MAY2018.	Non-Key
	25JUL2018 (115)	Visit Schedule	Hematology labs (15MAY2018) taken 2 days prior to dosing day C3D2 (17MAY2018), per protocol must be obtained within 24 hours of dosing.	Key
	25JUL2018 (115)	Visit Schedule	Hematology labs collected on 12JUN2018 greater than 24 hour prior to dosing on C4D2 on 14JUN2018.	Key
	31AUG2018 (152)	Laboratory	Cycle 4 Day 22 LDH not assessed on -2JUL2018.	Non-Key
	31AUG2018 (152)	Visit Schedule	Week 18 tumor assessments out of window. Subject 1145-003 Week 9 tumor assessments occurred 25MAY2018, therefore Week 18 tumor assessments are expected 27JUL2018 +/- 7 days. Instead the patient'sscans occured on 14AUGL2018.	Non-Key
	03OCT2018 (185)	Visit/Procedure Required	Immunologic Markers in Blood (PBMC) not collected for Cycle 7 Day 1 on 13SEP18.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1145003	09OCT2018 (191)	Visit Schedule	C6D1 Hematology labs (06AUG2018) obtained more than 24 hours before dosing (10AUG2018).	Key
	21NOV2018 (234)	Dosing	Subject 1145-003 received Trilaciclib on C9D1 on 08NOV2018 before eligibility was determined. The Patient had labs drawn on 08NOV2018, but the results were not available until 09NOV2018 which showedlow ANC of 0.8 and as a result treatment was held on C9D2.	Key
	27NOV2018 (240)	Visit Schedule	C8D1 Hematology labs (08OCT2018) not obtained within 24 hours of GC dosing on 12OCT2018.	Key
	19DEC2018 (262)	Dosing	No dose modifications were made at Cycle 9 once patient resumed treatment on 29NOV2018. Per protocol, either Gemcitabine or Carboplatin should have been discontinued.	Key
	19DEC2018 (262)	Dosing	Subject 11455-003 went more than 4 weeks without receiving treatment and restarted treatment without medical monitor permission. Per protocol, Dosing delays > 4 weeks may be permitted on acase-by-case basis with the approval of the investigator and medical monitor.The patient received C9D1 on 29NOV2018 the last dose before that was on C8D9 19OCT2018.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1145003	19DEC2018 (262)	Visit/Procedure Required	Immunologic Markers in Blood (PBMC) not collected for Cycle 9 Day 1 on 29NOV2018.	Non-Key
	12FEB2019 (317)	Laboratory	C9D15 hematology labs not collected on 14DEC2018.	Non-Key
	20FEB2019 (325)	Visit Schedule	Post Treatment Visit 1 (30Jan2019) was completed without performing vital signs, Physical Exam, or ECOG assessments and collecting FLOW and PBMC immunological samples.	Non-Key
	27FEB2019 (332)	Concomitant Medications	Subject 1145-03 received G-CSF (05DEC2018) less than 48 hours prior to C10D1 on 06DEC2018. Per protocol, Short-acting G-CSF products must be stopped 48 hours prior to trilaciclib administration inGroups 2 and 3.	Key
	21MAY2019 (415)	Visit Schedule	Cycle 6 Day 15 (27Aug2018) projected for 23-25Aug2018 was conducted out of window on 27Aug2018.	Non-Key
	23JUL2019 (478)	Visit Schedule	Survival Follow-up Tumor Assessment projected for 10Apr2019 (Â± 7 days) was completed on 25Mar2019.	Non-Key
	26JUL2019 (481)	Visit/Procedure Required	Post Treatment +60-days Visit (29Mar2019) PBMC and FLOW immunological samples were not collected.	Non-Key
	19AUG2019 (505)	Visit Schedule	Cycle 5 Day 15 visit projected for 26Jul2018 was conducted out of window on 30Jul2018.	Non-Key
	19AUG2019 (505)	Visit Schedule	Cycle 6 Day 1 (09Aug2018) was delayed using Cycle 5 Day 15 labs.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1145003	10OCT2019 (557)	Dosing	Cycle 7 was delayed and Carboplatin dose reduced based on Cycle 6 Day 15 labs.	Non-Key
	09APR2020 (739)	Visit/Procedure Required	Cycle 3 Day 1 PBMC immunological samples was not collected.	Non-Key
1145004	13JUN2018 (73)	Visit Schedule	Hematology (30APR2018) not obtained 24 hours prior to GC dosing on Cycle 2 Day 8/9.	Key
	13JUN2018 (73)	Visit Schedule	Respiratory Rate not completed during screening vitals on 12MAR2018.	Non-Key
	18JUL2018 (108)	Laboratory	Cycle 5 Day 1 LDH and Phosphorous not assessed on 25JUN2018.	Non-Key
	25JUL2018 (115)	Visit/Procedure Required	Cycle 2 FACT-An and B questionnaires not completed on 23APR2018.	Non-Key
	25JUL2018 (115)	Visit/Procedure Required	Immunologic Markers in Blood not collected Cycle 5 Day 1 on 25JUN2018.	Non-Key
	06AUG2018 (127)	Visit/Procedure Required	The C1D1 (02Apr2018) immunologic markers in blood were not collected.	Non-Key
	06AUG2018 (127)	Visit/Procedure Required	The C1D1 (02Apr2018) immunologic markers in tumor were not collected.	Non-Key
	06AUG2018 (127)	Visit/Procedure Required	The subject did not complete the FACT-A and FACT-B questionnaires at C5D1 on 25June2018	Non-Key
	07AUG2018 (128)	Laboratory	Hematology labs were not done for C2D8 on 30Apr2018.	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1145004	14AUG2018 (135)	Visit Schedule	Subject had Grade 3 ANC on 25JUN2018 (C5D1) but received treatment with G1T28. The safety labs were drawn in the morning before treatment but the results were not received before treating. Since itwas a Monday, the labs from Friday were used to determine eligibility for dosing.	Key
	31AUG2018 (152)	Visit Schedule	Week 9 tumor assessments out of window. Subject 1145-002 Week 9 tumor assessments were projected to occur 04JUN2018 +/- 7 days, instead the patient's scans occured on 12JUL2018.	Non-Key
	10MAY2019 (404)	Visit Schedule	Hematology (02JUN2018) not obtained 24 hours prior to GC dosing on Cycle 4 Day 1 (04JUN2018)	Key
1148001	14NOV2017 (28)	Laboratory	On C1D1 not all requested laboratory parameters were assessed and are marked as not done in the eCRF. PI couldn’t answer why this happened. Requisition form for local laboratory was completed as itwas always done before. When he contacted laboratory for rest of procedures, they stated that there is no more sample available. Chemistry parameters that were not performed: Ca, Cl, P, K, Na.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1148001	28MAY2018 (223)	Dosing	Protocol deviation occured for subject 1148001 during C9D1 visit. Value of Pletelets was 95 x 10^9/L on the day of visit, and subjects dosing was performed by omission of PI.	Non-Key
	11JUL2018 (267)	Dosing	Dose reduction of Carboplatin for subject #1148001 was not performed on Cy12D1 due to second episode of thrombocytopaenia	Non-Key
	27AUG2018 (314)	Visit Schedule	AE#16, Thrombocytopenia identified at C10 D15 was not followed within 7 days by PI, visit C10D22 was not performed and the C11D1 was delayed with 1 week.	Non-Key
	19MAR2019 (518)	Visit Schedule	Pt 1148001 should have FU TA on 26Feb2019 ± 7 days, but it was performed with dealy of 2 weeks, on 20Mar2019.	Non-Key
1148003	09JAN2019 (423)	Non-compliance	Patient had PD from 07Aug2018 but this was not identified by Site personnel. They did not compare to current SOD with smallest one. Due to this omission patient remained on study until 9 Jan 19.Patient should have been removed from treatment at the time PD was identified.	Key
	24MAY2019 (558)	Regulatory	Site has reported SAE for subject #1148003 out of timelines required by GCP and Study protocol. Site was aware of this SAE since the PTV 2 visit performed on 13Mar2019, and reported SAE via CRF on9May2019	Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1155001	20MAR2018 (125)	Laboratory	On C1D1 blood sample for PBMC was not collected for pt 001.	Non-Key
	02JUL2018 (229)	Laboratory	PD occurred on 03May2018, visit C9D1 on patient 001. PMBC was not collected.	Non-Key
1155003	28FEB2018 (42)	Visit/Procedure Required	Tumor assessment for patient 003 was performed on 22Feb2018, 6 weeks after the screening tumor assessment. This is tumor assessment schedule per PA#2. PA#3 was approved on 23Jan2018 and tumorassessment should be performed in 9 week time window.	Non-Key
	02JUL2018 (166)	Laboratory	On C3D1, 01Mar2018 blood sample for PBMC was not collected for pt 003.	Non-Key
	03AUG2018 (198)	Laboratory	Blood samples for immunology markers in blood not collected on C7D1 of patient 003.	Non-Key
1156003	24AUG2018 (201)	Visit Schedule	Post-Treatment Visit 2 for pt 003 was performed out of window - it was on 16Jul2018 which is approximately 30 days after the PTV1	Non-Key
1156004	28FEB2019 (389)	Dosing	C4D22 – 07May2018, 1st episode of thrombocytopenia. According to protocol at the occurrence of first episode of thrombocytopenia Gem dose should be reduced to 800mg/m2. Since the Gem was alreadyreduced due to non-haematology toxicity from the Cycle 1, site did not change anything. In cycle 5 dose of Gem was 800mg/m2 and AUC2 for Carbo.	Non-Key

Listing 16.2.2.2
Protocol Deviations
All enrolled patients

Subject Number	Date of Deviation (Study Day)	Deviation Type	Deviation Comment	Severity
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9				
1156004	28FEB2019 (389)	Non-compliance	Patient should be off the treatment during the Cycle 10 since dosing on C10D8 was skipped due to AE (decreased count of neutrophiles). Gem was alredy discontinued in Jul2018 and after that patien had2 cases of dose skipping due to AEs. Site was informed that patient should be discontinued, but disagree with CRA and CTL opinion.	Non-Key
1156005	24AUG2018 (184)	Visit/Procedure Required	According to Source Documents at visits C7D8 and C6D8, Vital Signs for patient 1156005 were not measured by site staff	Non-Key
1164001	19FEB2018 (-1)	Laboratory	Hematology testings will be preformed 48h before the chemotherapy administartion on D2 and D9 and not 24h as requested by the protocol. This is site standard procedure due to fact that lab is beinglocated in another city.	Key

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Screen Failure					
1017001					
1110001					
1110002					
1111006					
1113002					
1114004					
1116002					
1118004					
1120003					
1121003					
1123002					
1123003					
1124001					
1125004					
1126001					
1127002					
1129002					
1129003					
1129004					
1130002					
1131002					
1131003					
1131007					
1131008					
1131009					
1131012					
1133003					
1139001					
1145006					
1148002					

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Screen Failure					
1154001					
1154003					
1155002					
1156006					
1162001					
1163003					
1163004					
1163007					
1165002					
1171001					
Treatment: GC Therapy D1D8					
1017002	Yes	1	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN MESILATE) [HALAVEN]	24MAY2018 (210)	Ongoing
1110003					
1111005	Yes	1	INVESTIGATIONAL DRUG (INVESTIGATIONAL DRUG) [SGN-LIV1A]	07NOV2018 (289)	07NOV2018 (289)
	Yes	2	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE]	19DEC2018 (331)	2019
	Yes	3	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBULIN]	18FEB2019 (392)	25FEB2019 (399)
1112007	Yes	1	TAXANES (PACLITAXEL) [PACLITAXEL]	03OCT2018 (220)	Ongoing

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: GC Therapy D1D8					
1113003	Yes	1	OTHER ANTINEOPLASTIC AGENTS (OLAPARIB) [OLAPARIB]	15JAN2018 (112)	11JUN2018 (259)
	Yes	2	MONOCLONAL ANTIBODIES (PEMBROLIZUMAB) [PEMBROLIZUMAB]	17JUN2018 (265)	24SEP2018 (364)
	Yes	2	TAXANES (PACLITAXEL) [PACLITAXEL]	17JUN2018 (265)	24SEP2018 (364)
	Yes	3	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBULIN]	01FEB2019 (494)	25MAR2019 (546)
1114001					
1114002					
1114003					
1114005	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	20JUN2018 (93)	26JUL2018 (129)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	20JUN2018 (93)	26JUL2018 (129)
1116004	Yes	1	MONOCLONAL ANTIBODIES (PEMBROLIZUMAB) [PEMBROLIZUMAB]	20APR2018 (82)	Ongoing
	Yes	1	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBULIN]	20APR2018 (82)	Ongoing
1117001	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	21AUG2018 (226)	22AUG2018 (227)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: GC Therapy D1D8					
1117001	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	21AUG2018 (226)	22AUG2018 (227)
	Yes	1	TAXANES (PACLITAXEL ALBUMIN) [ABRAXANE]	18SEP2018 (254)	08JAN2019 (366)
1117005	Yes	1	INVESTIGATIONAL DRUG (INVESTIGATIONAL DRUG) [MMU-132 INVEST IV (SACITUZUMAB)]	09MAY2018 (80)	05SEP2018 (199)
	Yes	2	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBULIN]	16OCT2018 (240)	27NOV2018 (282)
1121002	Yes	1	TAXANES (DOCETAXEL) [DOCETAXEL]	29SEP2017 (93)	Ongoing
1123001					
1123004	Yes	1	TAXANES (PACLITAXEL ALBUMIN) [ABRAXANE]	31OCT2017 (63)	21NOV2017 (84)
1123005	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	14MAY2018 (231)	02JUL2018 (280)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	14MAY2018 (231)	02JUL2018 (280)
	Yes	1	PYRIMIDINE ANALOGUES (CAPECITABINE) [XELODA]	03JUL2018 (281)	04SEP2018 (344)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: GC Therapy D1D8					
1123005	Yes	2	TAXANES (PACLITAXEL ALBUMIN) [ABRAXANE]	13SEP2018 (353)	22FEB2019 (515)
1125006	Yes	1	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN MESILATE) [ERIBOLIN MESYLATE]	09MAY2018 (86)	13AUG2018 (182)
	Yes	1	MONOCLONAL ANTIBODIES (NIVOLUMAB) [NIVOLUMAB]	12JUN2018 (120)	10JUL2018 (148)
1128001	No				
1129001					
1131005					
1131006					
1131013	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE HYDROCHLORIDE) [GEMZAR]	03APR2019 (388)	12JUN2019 (458)
1131015	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE HYDROCHLORIDE) [GEMZAR]	20NOV2018 (261)	Ongoing
1131016					
1133001	Yes	1	MONOCLONAL ANTIBODIES (PEMBROLIZUMAB) [PEMBROLIZUMAB]	06DEC2017 (167)	22JAN2018 (214)
	Yes	1	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN MESILATE) [ERIBULIN MESYLATE]	06DEC2017 (167)	29JAN2018 (221)
	Yes		VARIOUS (RADIOTHERAPY) [RADIATION THERAPY]	16FEB2018 (239)	05MAR2018 (256)
1133004					

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: GC Therapy D1D8					
1137001	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	28JUN2018 (261)	16AUG2018 (310)
	Yes	1	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE (XELODA)]	31AUG2018 (325)	28NOV2018 (414)
1145001	Yes	1	PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	23MAR2018 (93)	23MAR2018 (93)
	Yes	1	PYRIMIDINE ANALOGUES (GEMCITABINE HYDROCHLORIDE) [GEMZAR]	23MAR2018 (93)	23MAR2018 (93)
	Yes	2	MONOCLONAL ANTIBODIES (PEMBROLIZUMAB) [PEMBROLIZAUMAB]	21JUN2018 (183)	20JUL2018 (212)
	Yes	2	OTHER ANTINEOPLASTIC AGENTS (OTHER ANTINEOPLASTIC AGENTS) [IMPRIME PGG (SOLUBLE, ß-1,3/1,6 GLUCAN)]	21JUN2018 (183)	26JUL2018 (218)
1148005	Yes	1	TAXANES (DOCETAXEL) [DOCETAXEL]	07JUL2018 (200)	13NOV2018 (329)
1154002	Yes	1	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINUM]	15MAY2018 (113)	20AUG2018 (210)
1156001	Yes		ALL OTHER THERAPEUTIC PRODUCTS (ALL OTHER THERAPEUTIC PRODUCTS) [QADRANTECTOMY OF LEFT BREAST]	20SEP2018 (270)	20SEP2018 (270)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: GC Therapy D1D8					
1156001	Yes		VARIOUS (RADIOTHERAPY) [RADIOTHERAPY TD 50GY/25 FRACTIONS TO THE LEFT AXXILA AND LEFT SUPRACLAVIUM]	15JAN2019 (387)	04MAR2019 (435)
	Yes		VARIOUS (RADIOTHERAPY) [RADIOTHERAPY TO THE LEFT BREAST TD 50GY/25 FRACTIONS WITH BOOST AT TUMOR BED TD16GY/8 FRACTIONS.]	15JAN2019 (387)	04MAR2019 (435)
1156007					
1163002	No				
1163006	No				
Treatment: Trilaciclib D1D8 + GC Therapy D1D8					
1111001	Yes	1	MONOCLONAL ANTIBODIES (SACITUZUMAB GOVITECAN) [SACITUZUMAB GOVITECAN]	2018	02JUN2018 (221)
1111003	No				
1112002	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	01AUG2017 (177)	07NOV2017 (275)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	01AUG2017 (177)	07NOV2017 (275)
1112004					

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1D8 + GC Therapy D1D8					
1113001	Yes		VARIOUS (RADIOTHERAPY) [WHOLE BRAIN RADIOTHERAPY-SHOWED NEW SMALL, METASTATIC LESIONS]	14MAY2018 (299)	01JUN2018 (317)
	Yes	1	PYRIMIDINE ANALOGUES (CAPECITABINE) [XELODA]	04JUN2018 (320)	JUN2019
	Yes		OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBULIN]	17JUN2019 (698)	DEC2019
	Yes		VINCA ALKALOIDS AND ANALOGUES (VINORELBINE) [VINORELBINE]	30DEC2019 (894)	Ongoing
1113004					
1117003	No				
1117004					
1121001	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	04AUG2017 (80)	18AUG2017 (94)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	04AUG2017 (80)	18AUG2017 (94)
	Yes	1	PYRIMIDINE ANALOGUES (CAPECITABINE) [XELODA]	14NOV2017 (182)	14FEB2018 (274)
	Yes	2	MONOCLONAL ANTIBODIES (PEMBROLIZUMAB) [PEMBROLIZUMAB]	21FEB2018 (281)	Ongoing

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1D8 + GC Therapy D1D8					
1121001	Yes	2	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN MESILATE) [ERIBULIN MESYLATE]	21FEB2018 (281)	Ongoing
1122001	Yes		TAXANES (PACLITAXEL) [PACLITAXEL]	19DEC2019 (809)	Ongoing
1124002	Yes		VARIOUS (RADIOTHERAPY) [RADIATION THERAPY TO LEFT NECK]	14MAR2018 (58)	30MAR2018 (74)
	Yes	1	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE]	14MAR2018 (58)	Ongoing
1125001	Yes	1	TAXANES (DOCETAXEL) [DOCETAXEL]	28SEP2018 (417)	29NOV2018 (479)
1125007					
1125008	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	25MAR2019 (316)	18JUN2019 (401)
1126003	Yes	1	TAXANES (PACLITAXEL) [PACLITAXEL]	25SEP2017 (81)	25SEP2017 (81)
	Yes	2	INVESTIGATIONAL DRUG (INVESTIGATIONAL DRUG) [SGN-LIV1A]	24OCT2017 (110)	07FEB2018 (216)
1126004	Yes	1	INVESTIGATIONAL DRUG (INVESTIGATIONAL DRUG) [INVESTIGATIONAL DRUG]	06FEB2018 (65)	27FEB2018 (86)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1D8 + GC Therapy D1D8					
1127001	Yes	1	TAXANES (PACLITAXEL ALBUMIN) [ABRAXANE]	29NOV2017 (51)	07FEB2018 (121)
	Yes	2	PROTEIN KINASE INHIBITORS (DABRAFENIB) [DABRAFENIB]	11MAY2018 (214)	Ongoing
	Yes	2	PROTEIN KINASE INHIBITORS (TRAMETINIB) [TRAMETINIB]	11MAY2018 (214)	Ongoing
1129005	Yes	1	MONOCLONAL ANTIBODIES (PEMBROLIZUMAB) [PEMBROLIZUMAB]	18APR2018 (164)	08MAY2019 (549)
	Yes	1	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBILIN]	18APR2018 (164)	15MAY2019 (556)
1131001					
1131011	Yes	1	PYRIMIDINE ANALOGUES (GEMCITABINE HYDROCHLORIDE) [GEMZAR]	26FEB2019 (387)	04JUN2019 (485)
	Yes		MONOCLONAL ANTIBODIES (ATEZOLIZUMAB) [ATEZOLIZUMAB]	16JUL2019 (527)	26NOV2019 (660)
	Yes		TAXANES (PACLITAXEL ALBUMIN) [ABRAXANE]	16JUL2019 (527)	03DEC2019 (667)
1131014	Yes	1	AROMATASE INHIBITORS (LETROZOLE) [FEMARA]	14JAN2019 (316)	23SEP2019 (568)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1D8 + GC Therapy D1D8					
1131014	Yes	1	PROTEIN KINASE INHIBITORS (EVEROLIMUS) [AFINITOR]	14JAN2019 (316)	23SEP2019 (568)
1133002	Yes	1	MONOCLONAL ANTIBODIES (PEMBROLIZUMAB) [PEMBROLIZUMAB]	11OCT2018 (367)	02JAN2019 (450)
	Yes	1	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBULIN]	11OCT2018 (367)	03JUL2019 (632)
	Yes		OTHER ANTINEOPLASTIC AGENTS (ERIBULIN MESILATE) [HALAVEN (ERIBULIN)]	12JUL2019 (641)	Ongoing
1133005					
1137002					
1141001	Yes	1	ANTHRACYCLINES AND RELATED SUBSTANCES (DOXORUBICIN HYDROCHLORIDE) [DOXORUBICIN HCL (ADRIAMYCIN)]	02MAR2018 (178)	02MAY2018 (239)
	Yes	1	NITROGEN MUSTARD ANALOGUES (CYCLOPHOSPHAMIDE) [CYCLOPHOSPHAMIDE INJ (CYTOXAN, NEOSAR)]	02MAR2018 (178)	02MAY2018 (239)
	Yes	1	TAXANES (PACLITAXEL) [PACLITAXEL INJ (TAXOL)]	24MAY2018 (261)	27SEP2018 (387)
1145002					
1145005					

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1D8 + GC Therapy D1D8					
1148004	Yes	1	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE]	APR2018	APR2018
1156002					
1163001	No				
1163005	Yes		VARIOUS (RADIOTHERAPY) [RADIOTHERAPY]	06MAY2019 (496)	07JUN2019 (528)
1165001	Yes		ALL OTHER THERAPEUTIC PRODUCTS (ALL OTHER THERAPEUTIC PRODUCTS) [TARGET LESION MALIGNANT TUMOR RESECTION RIGHT BREAST MASS LUMPECTOMY]	03AUG2018 (425)	03AUG2018 (425)
	Yes	1	PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	13SEP2018 (466)	01FEB2019 (607)
	Yes	1	PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	13SEP2018 (466)	01FEB2019 (607)
	Yes	2	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERBULIN]	05MAR2019 (639)	Ongoing
1166001	Yes		VARIOUS (RADIOTHERAPY) [RADIOTHERAPY]	15OCT2018 (222)	15OCT2018 (222)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1111002	Yes	1	INVESTIGATIONAL DRUG (INVESTIGATIONAL DRUG) [SGN-LIV1A]	24JAN2018 (44)	11APR2018 (121)
	Yes	2	PROTEIN KINASE INHIBITORS (CEDIRANIB) [CEDIRANIG]	16MAY2018 (156)	20JUN2018 (191)
	Yes	2	OTHER ANTINEOPLASTIC AGENTS (OLAPARIB) [OLAPARIB]	21MAY2018 (161)	20JUN2018 (191)
1111004	Yes	2	MONOCLONAL ANTIBODIES (SACITUZUMAB GOVITECAN) [SACITUZUMAB GOVITECAN]	2018	FEB2019
	Yes	1	ANTINEOPLASTIC AGENTS (ENTINOSTAT) [ENTINOSTAT]	AUG2018	OCT2018
	Yes	1	MONOCLONAL ANTIBODIES (ATEZOLIZUMAB) [ATEZOLIZUMAB]	AUG2018	OCT2018
	Yes	3	ANTHRACYCLINES AND RELATED SUBSTANCES (PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE) [DOXIL]	06MAR2019 (408)	02APR2019 (435)
	Yes	4	VINCA ALKALOIDS AND ANALOGUES (VINORELBINE) [VINORELBINE]	21MAY2019 (484)	JUN2019
1112001	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	30MAY2017 (117)	01AUG2017 (180)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1112001	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	30MAY2017 (117)	01AUG2017 (180)
	Yes	1	TAXANES (PACLITAXEL ALBUMIN) [ABRAXANE]	07NOV2017 (278)	20MAR2018 (411)
	Yes	2	INVESTIGATIONAL DRUG (INVESTIGATIONAL DRUG) [AZD6738]	25SEP2018 (600)	15JAN2019 (712)
	Yes	2	OTHER ANTINEOPLASTIC AGENTS (OLAPARIB) [OLAPARIB]	25SEP2018 (600)	15JAN2019 (712)
	Yes	3	PYRIMIDINE ANALOGUES (CAPECITABINE) [XELODA]	05APR2019 (792)	21MAY2019 (838)
	Yes	4	ANTHRACYCLINES AND RELATED SUBSTANCES (PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE) [DOXIL]	28MAY2019 (845)	30MAY2019 (847)
	Yes	5	MONOCLONAL ANTIBODIES (ATEZOLIZUMAB) [TECENTRIQ]	18JUN2019 (866)	10SEP2019 (950)
	Yes	5	TAXANES (PACLITAXEL ALBUMIN) [ABRAXANE]	18JUN2019 (866)	10SEP2019 (950)
1112006	Yes	1	INVESTIGATIONAL DRUG (INVESTIGATIONAL DRUG) [BGB324]	07NOV2017 (86)	04DEC2017 (113)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1112006	Yes	1	MONOCLONAL ANTIBODIES (PEMBROLIZUMAB) [PEMBROLIZUMAB]	07NOV2017 (86)	04DEC2017 (113)
1113005	Yes		ALL OTHER THERAPEUTIC PRODUCTS (ALL OTHER THERAPEUTIC PRODUCTS) [CANCER SURGERY]	24JAN2019 (388)	24JAN2019 (388)
	Yes		VARIOUS (RADIOTHERAPY) [RADIATION THERAPY]	06MAR2019 (429)	05APR2019 (459)
	Yes		PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE]	17AUG2019 (593)	22NOV2019 (690)
	Yes		OTHER ANTINEOPLASTIC AGENTS (POLY ADP-RIBOSE POLYMERASE INHIBITOR) [TALAZOPARIB]	05FEB2020 (765)	Ongoing
1116001	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	05JUN2018 (222)	24JUL2018 (271)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	05JUN2018 (222)	24JUL2018 (271)
	Yes	1	INVESTIGATIONAL DRUG (INVESTIGATIONAL DRUG) [INVESTIGATIONAL PRODUCT]	04OCT2018 (343)	25OCT2018 (364)
	Yes		PYRIMIDINE ANALOGUES (CAPECITABINE) [XELODA]	15JUL2019 (627)	Ongoing

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1116003	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	10APR2018 (75)	23APR2018 (88)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	10APR2018 (75)	30APR2018 (95)
	Yes	1	VINCA ALKALOIDS AND ANALOGUES (VINORELBINE TARTRATE) [VINORELBINE TARTRATE]	29MAY2018 (124)	09JAN2019 (349)
1117002					
1117006	Yes	1	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBULIN]	21NOV2018 (220)	11SEP2019 (514)
	Yes		OTHER ANTINEOPLASTIC AGENTS (ALPELISIB) [ALPELISB]	11SEP2019 (514)	09OCT2019 (542)
	Yes		ANTHRACYCLINES AND RELATED SUBSTANCES (DOXORUBICIN) [DOXORUBICIN]	10OCT2019 (543)	18NOV2019 (582)
1118001	Yes	1	PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	18JUL2017 (49)	05SEP2017 (98)
	Yes	1	PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	18JUL2017 (49)	05SEP2017 (98)
	Yes	2	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE]	20SEP2017 (113)	NOV2017

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1118002	Yes	1	MONOCLONAL ANTIBODIES (NIVOLUMAB) [NIVOLUMAB]	28JUN2018 (354)	26JUL2018 (382)
	Yes	2	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE]	11OCT2018 (459)	20NOV2018 (499)
	Yes	3	ANTHRACYCLINES AND RELATED SUBSTANCES (DOXORUBICIN HYDROCHLORIDE) [DOXO (LIPOSOMAL)]	29NOV2018 (508)	25APR2019 (655)
	Yes	4	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBULIN]	16MAY2019 (676)	17OCT2019 (830)
	Yes		VINCA ALKALOIDS AND ANALOGUES (VINORELBINE) [VINORELBINE]	19DEC2019 (893)	16JAN2020 (921)
1118003	Yes	1	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE (XELODA)]	09JAN2018 (114)	MAR2018
	Yes	2	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBILIN]	19MAR2018 (183)	01MAY2018 (226)
	Yes	3	ANTHRACYCLINES AND RELATED SUBSTANCES (DOXORUBICIN) [DOXORUBICIN]	30MAY2018 (255)	27JUN2018 (283)
1118005					
1120001					

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1120002	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	16MAY2018 (99)	11JUL2018 (155)
	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	30MAY2018 (113)	11JUL2018 (155)
	Yes	1	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN) [ERIBULIN]	25JUL2018 (169)	12DEC2018 (309)
	Yes	2	MONOCLONAL ANTIBODIES (PEMBROLIZUMAB) [PEMBROLIZUMAB]	05DEC2018 (302)	06MAR2019 (393)
	Yes	2	ANTHRACYCLINES AND RELATED SUBSTANCES (PEGYLATED LIPOSOMAL DOXORUBICIN HYDROCHLORIDE) [DOXIL]	02JAN2019 (330)	30JAN2019 (358)
	Yes	3	VINCA ALKALOIDS AND ANALOGUES (VINORELBINE) [VINORELBINE]	06MAR2019 (393)	15APR2019 (433)
1122002	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	10MAY2018 (193)	10JAN2019 (438)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	10MAY2018 (193)	10JAN2019 (438)
1122003					
1125002	Yes	1	TAXANES (PACLITAXEL) [PACLITAXEL]	29JAN2018 (127)	09APR2018 (197)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1125002	Yes	2	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN MESILATE) [ERIBULIN MESYLATE]	30APR2018 (218)	10AUG2018 (320)
	Yes	3	ANTHRACYCLINES AND RELATED SUBSTANCES (LIPOSOMAL DOXORUBICIN HYDROCHLORIDE) [LIPOSOMAL DOXORUBICIN HCL]	06SEP2018 (347)	12NOV2018 (414)
1125003					
1125005	Yes	1	OTHER ANTINEOPLASTIC AGENTS (OLAPARIB) [OLAPARIB]	18APR2018 (65)	13JUN2018 (121)
1126002	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	22JUN2017 (37)	19FEB2018 (279)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	22JUN2017 (37)	19FEB2018 (279)
	Yes		VARIOUS (RADIOTHERAPY) [RADIATION THERAPY]	27FEB2018 (287)	28MAR2018 (316)
	Yes	1	INVESTIGATIONAL DRUG (INVESTIGATIONAL DRUG) [SGN-LIV1A]	21JUN2018 (401)	25OCT2018 (527)
	Yes	2	OTHER ANTINEOPLASTIC AGENTS (ERIBULIN MESILATE) [ERIBULIN (HALAVEN)]	07JAN2019 (601)	05MAR2019 (658)
	Yes		VARIOUS (RADIOTHERAPY) [RADIATION THERAPY]	23APR2019 (707)	29MAY2019 (743)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1126002	Yes		VARIOUS (RADIOTHERAPY) [RADIATION THERAPY]	29JAN2020 (988)	20FEB2020 (1010)
	Yes		TAXANES (PACLITAXEL ALBUMIN) [ABRAXANE]	04FEB2020 (994)	Ongoing
1128002	Yes	1	AROMATASE INHIBITORS (ANASTROZOLE) [ANASTROZOLE]	19JUL2018 (130)	Ongoing
1130001	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	24APR2018 (177)	04JAN2019 (432)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	24APR2018 (177)	04JAN2019 (432)
	Yes	1	TAXANES (PACLITAXEL) [TAXOL]	25JAN2019 (453)	01OCT2019 (702)
	Yes		OTHER ANTINEOPLASTIC AGENTS (OLAPARIB) [OLAPARIB]	15OCT2019 (716)	Ongoing
1131004	Yes	1	PYRIMIDINE ANALOGUES (GEMCITABINE HYDROCHLORIDE) [GEMZAR]	14DEC2017 (150)	04JAN2018 (171)
	Yes	2	VINCA ALKALOIDS AND ANALOGUES (VINORELBINE) [VINORELBINE]	18JAN2018 (185)	16APR2018 (273)
	Yes	3	TAXANES (PACLITAXEL ALBUMIN) [ABRAXANE]	31MAY2018 (318)	Ongoing

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1131010					
1145003	Yes		PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	27FEB2019 (332)	27FEB2019 (332)
	Yes		PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	27FEB2019 (332)	27FEB2019 (332)
1145004					
1148001	No				
1148003					
1155001					
1155003					
1156003	Yes	1	TAXANES (DOCETAXEL) [DOCETAXEL]	13JUN2018 (129)	16AUG2018 (193)
	Yes	2	ANTHRACYCLINES AND RELATED SUBSTANCES (EPIRUBICIN) [EPIRUBICINE]	04OCT2018 (242)	04OCT2018 (242)
	Yes	2	NITROGEN MUSTARD ANALOGUES (CYCLOPHOSPHAMIDE) [CYCLOPHOSPHAMIDE]	04OCT2018 (242)	04OCT2018 (242)
1156004	Yes	1	PLATINUM COMPOUNDS (CARBOPLATIN) [CARBOPLATIN]	03APR2019 (423)	10APR2019 (430)
	Yes	1	PYRIMIDINE ANALOGUES (GEMCITABINE) [GEMCITABINE]	03APR2019 (423)	10APR2019 (430)

Listing 16.2.4.7.2
Subsequent Anti-Cancer Therapy
All enrolled patients

Subject Number	Subsequent Anti-Cancer Therapy	Line of Therapy	DRUG CLASSIFICATION (PREFERRED NAME) [Verbatim Name]	Start Date (Study Day)	End Date (Study Day)
Treatment: Trilaciclib D1_2D8_9 + GC Therapy D2D9					
1156004	Yes	2	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE]	07MAY2019 (457)	Ongoing
1156005					
1164001	Yes	1	PYRIMIDINE ANALOGUES (CAPECITABINE) [CAPECITABINE]	18MAR2019 (393)	01SEP2019 (560)

Listing 16.2.5.1.F
Study Drug Administration - Trilaciclib
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Total Volume Infused (mL)	Dose Interrupted/ Reason/Time (Restarted/Time)	Vial Number(s) Dispensed
Treatment: Trilaciclib D1D8 + GC Therapy D1D8										
1111003	1 / 1	18DEC2017 (1)	13:10/13:40	456.0	240.0	456	240.00	260.60	No	4471, 4472
	1 / 8	26DEC2017 (9)	16:41/17:11	456.0	240.0	456	240.00	260.60	No	4715, 4716
	2 / 1	08JAN2018 (22)	14:00/14:30	454.0	240.0	456	241.27	260.60	No	4723, 4724
	2 / 8	16JAN2018 (30)	16:50/17:20	454.0	240.0	456	241.27	260.60	No	4727, 4728
	3 / 1	29JAN2018 (43)	12:29/12:59	451.0	240.0	456	242.55	260.60	No	4741,4742
	4 / 1	19FEB2018 (64)	11:36/12:06	456.0	240.0	456	240.00	260.60	No	4753, 4754
	4 / 8	26FEB2018 (71)	11:21/11:51	456.0	240.0	456	240.00	260.60	No	2683, 2684
	5 / 1	12MAR2018 (85)	10:51/11:21	456.0	240.0	456	240.00	260.60	No	2831, 2832
	5 / 8	19MAR2018 (92)	15:49/16:19	456.0	240.0	456	240.00	260.60	No	2833, 2834
	6 / 1	02APR2018 (106)	11:11/11:41	456.0	240.0	456	240.00	260.60	No	4869, 4870
	6 / 8	09APR2018 (113)	15:48/16:18	456.0	240.0	456	240.00	260.60	No	4871, 4872
	7 / 1	23APR2018 (127)	10:56/11:26	456.0	240.0	456	240.00	260.60	No	4881, 4882
	7 / 8	30APR2018 (134)	16:29/16:59	456.0	240.0	456	240.00	260.60	No	5345, 5346
	8 / 1	14MAY2018 (148)	11:52/12:22	456.0	240.0	456	240.00	260.60	No	5355, 5356
	8 / 8	21MAY2018 (155)	14:53/15:23	456.0	240.0	456	240.00	260.60	No	5357, 5358
	9 / 1	04JUN2018 (169)	12:11/12:41	456.0	240.0	456	240.00	260.60	No	5643, 5644
	9 / 8	11JUN2018 (176)	17:21/17:51	456.0	240.0	456	240.00	260.60	No	5645, 5646
	10 / 1	25JUN2018 (190)	12:03/12:33	456.0	240.0	456	240.00	260.60	No	5719, 5720
	10 / 8	02JUL2018 (197)	15:04/15:34	456.0	240.0	456	240.00	292.00	No	5721, 5722
	11 / 1	16JUL2018 (211)	10:46/11:16	456.0	240.0	456	240.00	260.00	No	6550, 6551
	11 / 8	23JUL2018 (218)	16:42/17:12	456.0	240.0	456	240.00	260.60	No	6552, 6553
	12 / 1	07AUG2018 (233)	15:11/15:41	456.0	240.0	456	240.00	260.60	No	6554, 6555
	13 / 1	04SEP2018 (261)	13:07/13:37	456.0	240.0	456	240.00	260.60	No	6556, 6557
	13 / 8	10SEP2018 (267)	16:40/17:10	456.0	240.0	456	240.00	260.60	No	6558,6559
	14 / 1	24SEP2018 (281)	15:37/16:07	456.0	240.0	456	240.00	260.60	No	6560, 6561
	14 / 8	01OCT2018 (288)	15:47/16:17	456.0	240.0	456	240.00	260.60	No	6562, 6563
	15 / 1	15OCT2018 (302)	13:55/14:25	456.0	240.0	456	240.00	260.60	No	6564, 6565
	15 / 8	22OCT2018 (309)	16:08/16:38	456.0	240.0	456	240.00	260.60	No	6566, 6567

Listing 16.2.5.1.F
Study Drug Administration - Trilaciclib
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Total Volume Infused (mL)	Dose Interrupted/ Reason/Time (Restarted/Time)	Vial Number(s) Dispensed
Treatment: Trilaciclib D1D8 + GC Therapy D1D8										
1111003	16 / 1	05NOV2018 (323)	14:35/15:05	456.0	240.0	456	240.00	260.60	No	7340, 7341
	16 / 8	12NOV2018 (330)	15:44/16:14	456.0	240.0	456	240.00	260.60	No	7342, 7343
	17 / 1	26NOV2018 (344)	11:30/12:00	456.0	240.0	456	240.00	260.60	No	7344, 7345
	18 / 1	10DEC2018 (358)	13:24/13:54	456.0	240.0	456	240.00	260.60	No	7346, 7347
	19 / 1	07JAN2019 (386)	13:26/13:56	456.0	240.0	456	240.00	260.60	No	7348, 7349
	19 / 8	14JAN2019 (393)	15:30/16:00	456.0	240.0	456	240.00	260.60	No	7350, 7351
	20 / 1	30JAN2019 (409)	12:47/13:17	456.0	240.0	456	240.00	260.60	No	7352, 7353
	20 / 8	07FEB2019 (417)	14:44/15:14	456.0	240.0	456	240.00	260.60	No	7354, 7355
	21 / 1	18FEB2019 (428)	13:56/14:26	456.0	240.0	456	240.00	260.60	No	7356, 7357
	21 / 8	25FEB2019 (435)	15:14/15:46	456.0	240.0	456	240.00	260.60	No	7490, 7491
	22 / 1	18MAR2019 (456)	13:39/14:09	432.0	240.0	432	240.00	258.20	No	6568, 6569
	22 / 8	25MAR2019 (463)	14:40/15:10	432.0	240.0	432	240.00	258.20	No	6570, 6571
	23 / 1	08APR2019 (477)	13:31/14:01	432.0	240.0	432	240.00	258.20	No	6848, 6849
	23 / 8	15APR2019 (484)	15:52/16:22	432.0	240.0	432	240.00	258.20	No	6850, 6851
	24 / 1	29APR2019 (498)	11:50/12:20	432.0	240.0	432	240.00	258.20	No	6852, 6853
	24 / 8	06MAY2019 (505)	13:57/14:27	432.0	240.0	432	240.00	258.20	No	6854, 6855
	25 / 1	20MAY2019 (519)	11:12/11:42	432.0	240.0	432	240.00	258.20	No	6856, 6857
	25 / 8	28MAY2019 (527)	16:10/16:41	432.0	240.0	432	240.00	258.20	No	6858, 6859
	26 / 1	10JUN2019 (540)	11:33/12:03	432.0	240.0	432	240.00	258.20	No	6860,6861
	26 / 8	17JUN2019 (547)	16:23/16:53	432.0	240.0	432	240.00	258.20	No	6862, 6863
	27 / 1	01JUL2019 (561)	12:10/12:40	432.0	240.0	432	240.00	258.20	No	6864, 6865
	28 / 1	22JUL2019 (582)	11:59/12:29	432.0	240.0	432	240.00	258.20	No	6884,6885
	29 / 1	12AUG2019 (603)	12:03/12:33	432.0	240.0	432	240.00	258.20	No	6886 6887
1122001	1 / 1	04OCT2017 (3)	11:20/11:50	348.0	240.0	350	241.38	250.00	No	2417;2418
	1 / 8	11OCT2017 (10)	15:22/15:52	348.0	240.0	350	241.38	250.00	No	2419;2420
	2 / 1	25OCT2017 (24)	11:57/12:27	348.0	240.0	348	240.00	249.80	No	2421;2422
	2 / 8	01NOV2017 (31)	11:05/11:35	348.0	240.0	348	240.00	249.80	No	2427;2428
	3 / 1	15NOV2017 (45)	11:26/11:56	348.0	240.0	348	240.00	249.80	No	4401;4402

Listing 16.2.5.1.F
Study Drug Administration - Trilaciclib
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Total Volume Infused (mL)	Dose Interrupted/ Reason/Time (Restarted/Time)	Vial Number(s) Dispensed
Treatment: Trilaciclib D1D8 + GC Therapy D1D8										
1122001	3 /15	29NOV2017 (59)	11:05/11:35		240.0	348	240.00	249.80	No	4441;4442
	4 / 1	13DEC2017 (73)	11:28/11:58	348.0	240.0	348	240.00	249.80	No	4447;4448
	4 / 8	20DEC2017 (80)	13:15/13:45	348.0	240.0	348	240.00	249.80	No	4567;4568
	5 / 1	03JAN2018 (94)	11:20/11:50	348.0	240.0	348	240.00	249.80	No	4573;4574
	5 / 8	10JAN2018 (101)	11:20/11:50	348.0	240.0	348	240.00	249.80	No	4575;4576
	6 / 1	24JAN2018 (115)	11:48/12:18	348.0	240.0	348	240.00	249.80	No	4647;4648
	6 / 8	31JAN2018 (122)	11:34/12:04	348.0	240.0	348	240.00	249.80	No	4649;4650
	7 / 1	14FEB2018 (136)	12:10/12:40	348.0	240.0	348	240.00	249.80	No	4821;4822
	7 / 8	21FEB2018 (143)	11:55/12:25	348.0	240.0	348	240.00	249.80	No	4823;4824
	8 / 1	07MAR2018 (157)	12:15/12:45	348.0	240.0	348	240.00	249.80	No	5059;5060
	8 / 8	14MAR2018 (164)	11:15/11:45	348.0	240.0	348	240.00	249.80	No	5065;5066
	9 / 1	29MAR2018 (179)	10:39/11:09	348.0	240.0	348	240.00	249.80	No	5071,5072
	9 / 8	04APR2018 (185)	11:45/12:20	348.0	240.0	348	240.00	249.80	No	5225,5226
	10 / 1	18APR2018 (199)	11:41/12:11	348.0	240.0	348	240.00	249.80	No	5235;5236
	10 / 8	25APR2018 (206)	11:51/12:22	348.0	240.0	348	240.00	249.80	No	5431;5432
	11 / 1	09MAY2018 (220)	12:33/13:03	348.0	240.0	348	240.00	249.80	No	5433;5434
	11 / 8	16MAY2018 (227)	11:53/12:23	348.0	240.0	348	240.00	249.80	No	5435;5436
	12 / 1	30MAY2018 (241)	13:50/14:20	348.0	240.0	348	240.00	249.80	No	5437;5438
	12 / 8	06JUN2018 (248)	14:11/14:41	348.0	240.0	348	240.00	249.80	No	5439;5440
	13 / 1	20JUN2018 (262)	12:30/13:00	348.0	240.0	348	240.00	249.80	No	5441;5442
	13 / 8	27JUN2018 (269)	12:35/13:05	348.0	240.0	348	240.00	249.80	No	5443;5444
	14 / 1	11JUL2018 (283)	10:50/11:20	348.0	240.0	348	240.00	249.80	No	5445;5446
	14 / 8	18JUL2018 (290)	12:10/12:40	348.0	240.0	348	240.00	249.80	No	5447;5448
	15 / 1	01AUG2018 (304)	12:55/13:25	348.0	240.0	348	240.00	249.80	No	5239;5240
	15 / 8	08AUG2018 (311)	14:27/14:57	348.0	240.0	348	240.00	249.80	No	5241;5242
	16 / 1	22AUG2018 (325)	12:40/13:10	348.0	240.0	348	240.00	249.80	No	5449;5450
	16 / 8	29AUG2018 (332)	14:20/14:50	348.0	240.0	348	240.00	249.80	No	5451;5452
	17 / 1	12SEP2018 (346)	11:44/12:14	348.0	240.0	348	240.00	249.80	No	6644;6645

Listing 16.2.5.1.F
Study Drug Administration - Trilaciclib
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Total Volume Infused (mL)	Dose Interrupted/ Reason/Time (Restarted/Time)	Vial Number(s) Dispensed
Treatment: Trilaciclib D1D8 + GC Therapy D1D8										
1122001	17 / 8	19SEP2018 (353)	14:55/15:25	348.0	240.0	348	240.00	249.80	No	6646;6647
	18 / 1	03OCT2018 (367)	11:30/12:00	348.0	240.0	348	240.00	249.80	No	6648;6649
	18 / 8	10OCT2018 (374)	11:55/12:35	348.0	240.0	348	240.00	249.80	No	6650;6651
	19 / 1	24OCT2018 (388)	12:32/13:02	348.0	240.0	348	240.00	249.80	No	6652;6653
	19 / 8	31OCT2018 (395)	11:45/12:15	348.0	240.0	348	240.00	249.80	No	7358;7359
	20 / 1	14NOV2018 (409)	11:25/11:55	348.0	240.0	348	240.00	249.80	No	7360;7361
	20 / 8	21NOV2018 (416)	13:45/14:15	348.0	240.0	348	240.00	249.80	No	7362;7363
	21 / 1	05DEC2018 (430)	12:00/12:30	348.0	240.0	348	240.00	249.80	No	7364;7365
	21 / 8	12DEC2018 (437)	14:22/14:52	348.0	240.0	348	240.00	249.80	No	7366;7367
	22 / 1	26DEC2018 (451)	12:20/12:50	348.0	240.0	348	240.00	249.80	No	7368;7369
	22 / 8	02JAN2019 (458)	14:30/15:00	348.0	240.0	348	240.00	249.80	No	7424;7425
	23 / 1	16JAN2019 (472)	13:23/13:53	348.0	240.0	348	240.00	249.80	No	7426;7427
	23 / 8	23JAN2019 (479)	10:50/11:20	348.0	240.0	348	240.00	249.80	No	7428;7429
	24 / 1	06FEB2019 (493)	13:17/13:47	348.0	240.0	348	240.00	249.80	No	7430;7431
	24 / 8	13FEB2019 (500)	11:45/12:15	348.0	240.0	348	240.00	249.80	No	7432;7433
	25 / 1	27FEB2019 (514)	12:45/13:15	348.0	240.0	348	240.00	249.80	No	7434, 7435
	25 / 8	06MAR2019 (521)	12:00/12:30	348.0	240.0	348	240.00	249.80	No	6654, 6655
	26 / 1	20MAR2019 (535)	10:56/11:26	348.0	240.0	348	240.00	249.80	No	7514, 7515
	26 / 8	27MAR2019 (542)	10:45/11:15	348.0	240.0	348	240.00	249.80	No	7516,7517
	28 / 1	01MAY2019 (577)	12:34/13:04	348.0	240.0	348	240.00	249.80	No	7518, 7519
	28 / 8	08MAY2019 (584)	13:00/13:30	348.0	240.0	348	240.00	249.80	No	7520, 7521
	29 / 1	22MAY2019 (598)	11:58/12:28	348.0	240.0	348	240.00	249.80	No	4397, 4398
	29 / 8	29MAY2019 (605)	12:39/13:09	348.0	240.0	348	240.00	249.80	No	4399, 4400
	30 / 1	12JUN2019 (619)	11:36/12:06	348.0	240.0	348	240.00	249.80	No	7522, 7523
	30 / 8	19JUN2019 (626)	11:52/12:22	348.0	240.0	348	240.00	249.80	No	7524, 7525
	31 / 1	10JUL2019 (647)	12:20/12:50	348.0	240.0	348	240.00	249.80	No	6866, 6867
	31 / 8	17JUL2019 (654)	13:27/13:57	348.0	240.0	348	240.00	249.80	No	6868, 6869
	32 / 1	07AUG2019 (675)	13:04/13:34	348.0	240.0	348	240.00	249.80	No	6870, 6871

Listing 16.2.5.1.F
Study Drug Administration - Trilaciclib
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Total Volume Infused (mL)	Dose Interrupted/ Reason/Time (Restarted/Time)	Vial Number(s) Dispensed
Treatment: Trilaciclib D1D8 + GC Therapy D1D8										
1122001	33 / 1	21AUG2019 (689)	11:35/12:05	348.0	240.0	348	240.00	249.80	No	6872, 6873
	33 / 8	28AUG2019 (696)	11:50/12:32	348.0	240.0	348	240.00	249.80	No	6874, 6875

Listing 16.2.5.2.F
Study Drug Administration - Carboplatin
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (AUC)	Actual Dose (mg)	Derived Dose (AUC)	GFR Used for Dose Calculation	Method Used to Calculate GFR	GFR Value	Dose Interrupted/ Reason/Time (Restarted/Time)
Treatment: Trilaciclib D1D8 + GC Therapy D1D8											
1111003	1 / 1	18DEC2017 (1)	14:22/15:22	170.0	2.0	170.00	2.00		Cockcroft gault	60.00	No
	1 / 8	26DEC2017 (9)	18:08/19:08	170.0	2.0	170.00	2.00		Cockcroft gault	60.00	No
	2 / 1	08JAN2018 (22)	15:21/16:21	160.0	2.0	160.00	2.01		Cockcroft gault	54.50	No
	2 / 8	16JAN2018 (30)	18:16/19:16	160.0	2.0	160.00	2.01		Cockcroft gault	54.50	No
	3 / 1	29JAN2018 (43)	13:50/14:50	160.0	2.0	160.00	2.01		Cockcroft gault	54.50	No
	4 / 1	19FEB2018 (64)	13:01/14:01	170.0	2.0	170.00	2.02		Cockcroft gault	59.00	No
	4 / 8	26FEB2018 (71)	13:24/15:24	170.0	2.0	170.00	2.02		Cockcroft gault	59.00	No
	5 / 1	12MAR2018 (85)	12:22/14:22	170.0	2.0	170.00	2.02		Cockcroft gault	59.00	No
	5 / 8	19MAR2018 (92)	17:19/19:19	170.0	2.0	170.00	2.02		Cockcroft gault	59.00	No
	6 / 1	02APR2018 (106)	13:12/15:12	170.0	2.0	170.00	2.01		Cockcroft gault	59.40	No
	6 / 8	09APR2018 (113)	17:29/19:22	170.0	2.0	170.00	2.01		Cockcroft gault	59.40	No
	7 / 1	23APR2018 (127)	12:37/14:37	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	7 / 8	30APR2018 (134)	18:10/20:10	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	8 / 1	14MAY2018 (148)	13:49/15:49	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	8 / 8	21MAY2018 (155)	16:32/18:32	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	9 / 1	04JUN2018 (169)	13:27/15:27	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	9 / 8	11JUN2018 (176)	19:06/21:06	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	10 / 1	25JUN2018 (190)	13:52/15:45	170.0	2.0	170.00	2.01		Cockcroft gault	59.40	No
	10 / 8	02JUL2018 (197)	17:06/19:06	170.0	2.0	170.00	2.15		Cockcroft gault	54.00	No
	11 / 1	16JUL2018 (211)	12:31/14:31	170.0	2.0	170.00	2.01		Cockcroft gault	59.40	No
	11 / 8	23JUL2018 (218)	18:30/20:28	170.0	2.0	170.00	2.01		Cockcroft gault	59.40	No
	12 / 1	07AUG2018 (233)	17:34/19:34	150.0	2.0	150.00	2.00		Cockcroft gault	50.00	No
	13 / 1	04SEP2018 (261)	14:53/16:53	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	13 / 8	10SEP2018 (267)	18:24/20:20	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	14 / 1	24SEP2018 (281)	17:26/19:26	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	14 / 8	01OCT2018 (288)	17:41/19:41	160.0	2.0	160.00	2.03		Cockcroft gault	54.00	No
	15 / 1	15OCT2018 (302)	15:37/17:37	170.0	2.0	170.00	2.02		Cockcroft gault	59.00	No
	15 / 8	22OCT2018 (309)	18:06/20:06	170.0	2.0	170.00	2.02		Cockcroft gault	59.00	No

Note: Any missing planned dose is due to patient receiving unplanned dose which was not able to be collected in the database.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_drug_f.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.5.2.F
Study Drug Administration - Carboplatin
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (AUC)	Actual Dose (mg)	Derived Dose (AUC)	GFR Used for Dose Calculation	Method Used to Calculate GFR	GFR Value	Dose Interrupted/ Reason/Time (Restarted/Time)
Treatment: Trilaciclib D1D8 + GC Therapy D1D8											
1111003	16 / 1	05NOV2018 (323)	16:31/18:31	150.0	2.0	150.00	2.00		Cockcroft gault	50.00	No
	16 / 8	12NOV2018 (330)	17:29/19:29	150.0	2.0	150.00	2.00		Cockcroft gault	50.00	No
	17 / 1	26NOV2018 (344)	13:11/15:11	170.0	2.0	170.00	2.02		Cockcroft gault	59.00	No
	18 / 1	10DEC2018 (358)	15:19/17:19	150.0	2.0	150.00	2.00		Cockcroft gault	50.00	No
	19 / 1	07JAN2019 (386)	15:12/17:09	120.0	1.5	120.00	1.52		Cockcroft gault	54.00	No
	19 / 8	14JAN2019 (393)	17:10/19:10	120.0	1.5	120.00	1.52		Cockcroft gault	54.00	No
1122001	1 / 1	04OCT2017 (3)	13:00/13:30	214.0	2.0	214.00	1.61		CKD-EPI	107.85	No
	1 / 8	11OCT2017 (10)	16:24/16:54	214.0	2.0	191.00	1.65		CKD-EPI	90.44	No
	2 / 1	25OCT2017 (24)	13:08/13:38	266.0	2.0	266.00	2.00		CKD-EPI	107.80	No
	2 / 8	01NOV2017 (31)	12:30/13:00	266.0	2.0	266.00	2.00		CKD-EPI	107.79	No
	3 / 1	15NOV2017 (45)	12:39/13:09	264.0	2.0	264.00	2.00		CKD-EPI	107.24	No
	3 /15	29NOV2017 (59)	12:35/13:05	264.0	2.0	264.00	1.94		CKD-EPI	111.11	No
	4 / 1	13DEC2017 (73)	12:30/13:00	264.0	2.0	264.00	1.89		CKD-EPI	114.93	No
	4 / 8	20DEC2017 (80)	13:50/14:20	264.0	2.0	264.00	1.82		CKD-EPI	120.17	No
	5 / 1	03JAN2018 (94)	12:45/13:15	264.0	2.0	264.00	2.13		CKD-EPI	99.22	No
	5 / 8	10JAN2018 (101)	13:20/14:10	232.0	2.0	232.00	1.69		CKD-EPI	112.24	No
	6 / 1	24JAN2018 (115)	12:20/12:50	209.0	2.0	209.00	1.58		CKD-EPI	107.61	No
	6 / 8	31JAN2018 (122)	12:17/12:47	209.0	2.0	209.00	1.54		CKD-EPI	110.38	No
	7 / 1	14FEB2018 (136)	13:16/13:46	209.0	2.0	209.00	1.58		CKD-EPI	107.57	No
	7 / 8	21FEB2018 (143)	13:05/13:35	236.0	2.0	236.00	1.73		CKD-EPI	111.53	No
	8 / 1	07MAR2018 (157)	13:20/13:50	236.0	2.0	236.00	1.73		CKD-EPI	111.50	No
	8 / 8	14MAR2018 (164)	12:25/12:55	205.0	2.0	205.00	1.54		CKD-EPI	108.05	No
	9 / 1	29MAR2018 (179)	11:45/12:15	154.0	1.5	154.00	1.15		CKD-EPI	108.56	No
	9 / 8	04APR2018 (185)	13:00/13:30	154.0	1.5	154.00	1.19		CKD-EPI	104.13	No
	10 / 1	18APR2018 (199)	12:51/13:21	158.0	1.5	158.00	1.19		CKD-EPI	107.97	No
	10 / 8	25APR2018 (206)	12:55/13:25	175.0	1.5	175.00	1.29		CKD-EPI	110.20	No
	11 / 1	09MAY2018 (220)	13:51/14:21	178.0	1.5	178.00	1.30		CKD-EPI	111.98	No
	11 / 8	16MAY2018 (227)	13:00/13:30	159.0	1.5	159.00	1.20		CKD-EPI	107.91	No

Note: Any missing planned dose is due to patient receiving unplanned dose which was not able to be collected in the database.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_drug_f.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.5.2.F
Study Drug Administration - Carboplatin
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (AUC)	Actual Dose (mg)	Derived Dose (AUC)	GFR Used for Dose Calculation	Method Used to Calculate GFR	GFR Value	Dose Interrupted/ Reason/Time (Restarted/Time)
Treatment: Trilaciclib D1D8 + GC Therapy D1D8											
1122001	12 / 1	30MAY2018 (241)	14:50/15:20	159.0	1.5	159.00	1.20		CKD-EPI	107.89	No
	12 / 8	06JUN2018 (248)	15:18/15:48	124.0	1.5	124.00	1.29		CKD-EPI	71.32	No
	13 / 1	20JUN2018 (262)	13:36/14:06	162.0	1.5	162.00	1.26		CKD-EPI	103.98	No
	13 / 8	27JUN2018 (269)	13:40/14:10	181.0	1.5	181.00	1.33		CKD-EPI	110.66	No
	14 / 1	11JUL2018 (283)	11:52/12:22	183.0	1.5	183.00	1.37		CKD-EPI	108.90	No
	14 / 8	18JUL2018 (290)	13:15/13:45	146.0	1.5	146.00	1.21		CKD-EPI	95.71	No
	15 / 1	01AUG2018 (304)	14:05/14:45	163.0	1.5	163.00	1.23		CKD-EPI	107.22	No
	15 / 8	08AUG2018 (311)	15:33/16:08	163.0	1.5	163.00	1.24		CKD-EPI	106.69	No
	16 / 1	22AUG2018 (325)	14:00/14:30	184.0	1.5	184.00	1.36		CKD-EPI	109.95	No
	16 / 8	29AUG2018 (332)	15:28/16:00	164.0	1.5	164.00	1.24		CKD-EPI	107.70	No
	17 / 1	12SEP2018 (346)	12:50/13:20	166.0	1.5	166.00	1.25		CKD-EPI	107.67	No
	17 / 8	19SEP2018 (353)	16:10/16:40	167.0	1.5	167.00	1.25		CKD-EPI	108.20	No
	18 / 1	03OCT2018 (367)	12:33/13:03	165.0	1.5	165.00	1.32		CKD-EPI	100.34	No
	18 / 8	10OCT2018 (374)	13:10/13:45	187.0	1.5	187.00	1.37		CKD-EPI	111.65	No
	19 / 1	24OCT2018 (388)	13:35/14:05	168.0	1.5	168.00	1.31		CKD-EPI	103.72	No
	19 / 8	31OCT2018 (395)	12:50/13:20	168.0	1.5	168.00	1.28		CKD-EPI	106.01	No
	20 / 1	14NOV2018 (409)	12:40/13:10	168.0	1.5	168.00	1.29		CKD-EPI	105.48	No
	20 / 8	21NOV2018 (416)	14:45/15:15	151.0	1.5	151.00	1.35		CKD-EPI	87.10	No
	21 / 1	05DEC2018 (430)	13:00/13:30	169.0	1.5	169.00	1.29		CKD-EPI	106.44	No
	21 / 8	12DEC2018 (437)	15:27/15:57	191.0	1.5	191.00	1.43		CKD-EPI	108.57	No
	22 / 1	26DEC2018 (451)	13:20/13:50	191.0	1.5	191.00	1.43		CKD-EPI	108.53	No
	22 / 8	02JAN2019 (458)	15:32/16:02	167.0	1.5	167.00	1.28		CKD-EPI	105.37	No
	23 / 1	16JAN2019 (472)	14:30/15:00	189.0	1.5	189.00	1.42		CKD-EPI	108.49	No
	23 / 8	23JAN2019 (479)	11:55/12:25	167.0	1.5	167.00	1.28		CKD-EPI	105.82	No
	24 / 1	06FEB2019 (493)	14:20/14:50	167.0	1.5	167.00	1.26		CKD-EPI	107.89	No
	24 / 8	13FEB2019 (500)	13:06/13:36	189.0	1.5	189.00	1.40		CKD-EPI	109.57	No
	25 / 1	27FEB2019 (514)	13:54/14:24	167.0	1.5	167.00	1.26		CKD-EPI	107.31	No
	25 / 8	06MAR2019 (521)	13:16/13:46	189.0	1.5	189.00	1.40		CKD-EPI	109.52	No

Note: Any missing planned dose is due to patient receiving unplanned dose which was not able to be collected in the database.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_drug_f.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.5.2.F
Study Drug Administration - Carboplatin
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (AUC)	Actual Dose (mg)	Derived Dose (AUC)	GFR Used for Dose Calculation	Method Used to Calculate GFR	GFR Value	Dose Interrupted/ Reason/Time (Restarted/Time)
Treatment: Trilaciclib D1D8 + GC Therapy D1D8											
1122001	26 / 1	20MAR2019 (535)	11:59/12:29	188.0	1.5	188.00	1.38		CKD-EPI	111.30	No
	26 / 8	27MAR2019 (542)	11:47/12:20	186.0	1.5	186.00	1.39		CKD-EPI	108.91	No
	28 / 1	01MAY2019 (577)	13:41/14:11	144.0	1.5	144.00	1.50		Cockcroft gault	71.00	No
	28 / 8	08MAY2019 (584)	14:05/14:35	144.0	1.5	144.00	1.50		Cockcroft gault	71.00	No
	29 / 1	22MAY2019 (598)	13:00/13:30	160.0	1.5	160.00	1.50		Cockcroft gault	82.00	No
	29 / 8	29MAY2019 (605)	13:50/14:20	160.0	1.5	160.00	1.50		Cockcroft gault	82.00	No
	30 / 1	12JUN2019 (619)	12:38/13:08	160.0	1.5	160.00	1.50		Cockcroft gault	82.00	No
	30 / 8	19JUN2019 (626)	12:52/13:22	160.0	1.5	160.00	1.50		Cockcroft gault	81.90	No
	31 / 1	10JUL2019 (647)	13:33/14:03	160.0	1.5	160.00	1.48		Cockcroft gault	83.00	No
	31 / 8	17JUL2019 (654)	14:30/15:00	183.0	1.5	183.00	1.50		Cockcroft gault	97.00	No
	32 / 1	07AUG2019 (675)	14:06/14:36	163.0	1.5	163.00	1.50		Cockcroft gault	84.00	No
	33 / 1	21AUG2019 (689)	12:40/13:10	163.0	1.5	163.00	1.50		Cockcroft gault	84.00	No
	33 / 8	28AUG2019 (696)	13:06/13:36	163.0	1.5	163.00	1.50		Cockcroft gault	84.00	No

Note: Any missing planned dose is due to patient receiving unplanned dose which was not able to be collected in the database.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_drug_f.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.5.3.F
Study Drug Administration - Gemcitabine
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Dose Interrupted/ Reason/Time (Restarted/Time)	BSA
Treatment: Trilaciclib D1D8 + GC Therapy D1D8									
1111003	1 / 1	18DEC2017 (1)	13:48/14:18	1900.0	1000.0	1900	1000.00	No	1.90
	1 / 8	26DEC2017 (9)	17:21/17:51	1900.0	1000.0	1900	1000.00	No	1.90
	2 / 1	08JAN2018 (22)	14:46/15:16	1900.0	1000.0	1900	1005.29	No	1.89
	2 / 8	16JAN2018 (30)	17:34/18:04	1900.0	1000.0	1900	1005.29	No	1.89
	3 / 1	29JAN2018 (43)	13:10/13:40	1900.0	1000.0	1900	1010.64	No	1.88
	4 / 1	19FEB2018 (64)	12:18/12:48	1900.0	1000.0	1900	1000.00	No	1.90
	4 / 8	26FEB2018 (71)	12:20/12:50	1900.0	1000.0	1900	1000.00	No	1.90
	5 / 1	12MAR2018 (85)	11:51/12:21	1900.0	1000.0	1900	1000.00	No	1.90
	5 / 8	19MAR2018 (92)	16:43/17:13	1900.0	1000.0	1900	1000.00	No	1.90
	6 / 1	02APR2018 (106)	11:55/12:25	1900.0	1000.0	1900	1000.00	No	1.90
	6 / 8	09APR2018 (113)	16:26/16:56	1900.0	1000.0	1900	1000.00	No	1.90
	7 / 1	23APR2018 (127)	11:41/12:11	1900.0	1000.0	1900	1000.00	No	1.90
	7 / 8	30APR2018 (134)	17:07/17:37	1900.0	1000.0	1900	1000.00	No	1.90
	8 / 1	14MAY2018 (148)	12:34/13:04	1900.0	1000.0	1900	1000.00	No	1.90
	8 / 8	21MAY2018 (155)	15:31/16:01	1900.0	1000.0	1900	1000.00	No	1.90
	9 / 1	04JUN2018 (169)	12:49/13:19	1900.0	1000.0	1900	1000.00	No	1.90
	9 / 8	11JUN2018 (176)	17:58/18:28	1900.0	1000.0	1900	1000.00	No	1.90
	10 / 1	25JUN2018 (190)	12:42/13:12	1900.0	1000.0	1900	1000.00	No	1.90
	10 / 8	02JUL2018 (197)	15:47/16:17	1900.0	1000.0	1900	1000.00	No	1.90
	11 / 1	16JUL2018 (211)	11:26/11:56	1900.0	1000.0	1900	1000.00	No	1.90
	11 / 8	23JUL2018 (218)	17:21/17:51	1900.0	1000.0	1900	1000.00	No	1.90
	12 / 1	07AUG2018 (233)	16:26/16:56	1900.0	1000.0	1900	1000.00	No	1.90
	13 / 1	04SEP2018 (261)	13:46/14:16	1900.0	1000.0	1900	1000.00	No	1.90
	13 / 8	10SEP2018 (267)	17:16/17:46	1900.0	1000.0	1900	1000.00	No	1.90
	14 / 1	24SEP2018 (281)	16:20/16:50	1900.0	1000.0	1900	1000.00	No	1.90
	14 / 8	01OCT2018 (288)	16:25/16:55	1900.0	1000.0	1900	1000.00	No	1.90
	15 / 1	15OCT2018 (302)	14:30/15:00	1900.0	1000.0	1900	1000.00	No	1.90
	15 / 8	22OCT2018 (309)	16:53/17:23	1900.0	1000.0	1900	1000.00	No	1.90

Note: Any missing planned dose is due to patient receiving unplanned dose which was not able to be collected in the database.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_drug_f.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.5.3.F
Study Drug Administration - Gemcitabine
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Dose Interrupted/ Reason/Time (Restarted/Time)	BSA
Treatment: Trilaciclib D1D8 + GC Therapy D1D8									
1111003	16 / 1	05NOV2018 (323)	15:18/15:48	1900.0	1000.0	1900	1000.00	No	1.90
	16 / 8	12NOV2018 (330)	16:19/16:49	1900.0	1000.0	1900	1032.61	No	1.84
	17 / 1	26NOV2018 (344)	12:08/12:38	1900.0	1000.0	1900	1000.00	No	1.90
	18 / 1	10DEC2018 (358)	14:06/14:36	1900.0	1000.0	1900	1000.00	No	1.90
	19 / 1	07JAN2019 (386)	14:06/14:36	1520.0	800.0	1520	800.00	No	1.90
	19 / 8	14JAN2019 (393)	16:04/16:34	1520.0	800.0	1520	800.00	No	1.90
	20 / 1	30JAN2019 (409)	13:25/13:55	1520.0	800.0	1520	800.00	No	1.90
	20 / 8	07FEB2019 (417)	15:21/15:51	1520.0	800.0	1520	826.09	No	1.84
	21 / 1	18FEB2019 (428)	14:35/15:05	1520.0	800.0	1520	800.00	No	1.90
	21 / 8	25FEB2019 (435)	15:52/16:20	1520.0	800.0	1520	800.00	No	1.90
	22 / 1	18MAR2019 (456)	14:22/14:52	1444.0	800.0	1444	802.22	No	1.80
	22 / 8	25MAR2019 (463)	15:25/15:55	1444.0	800.0	1444	802.22	No	1.80
	23 / 1	08APR2019 (477)	14:05/14:35	1444.0	800.0	1444	802.22	No	1.80
	23 / 8	15APR2019 (484)	16:29/16:59	1444.0	800.0	1444	802.22	No	1.80
	24 / 1	29APR2019 (498)	12:29/12:59	1444.0	800.0	1444	802.22	No	1.80
	24 / 8	06MAY2019 (505)	14:37/15:07	1444.0	800.0	1444	797.79	No	1.81
	25 / 1	20MAY2019 (519)	11:48/12:18	1444.0	800.0	1444	802.22	No	1.80
	25 / 8	28MAY2019 (527)	16:46/17:16	1444.0	800.0	1444	802.22	No	1.80
	26 / 1	10JUN2019 (540)	12:08/12:38	1444.0	800.0	1444	802.22	No	1.80
	26 / 8	17JUN2019 (547)	16:58/17:28	1444.0	800.0	1444	802.22	No	1.80
	27 / 1	01JUL2019 (561)	12:48/13:18	1444.0	800.0	1444	802.22	No	1.80
	28 / 1	22JUL2019 (582)	12:36/13:06	1444.0	800.0	1444	802.22	No	1.80
	29 / 1	12AUG2019 (603)	12:38/13:08	1444.0	800.0	1444	802.22	No	1.80
1122001	1 / 1	04OCT2017 (3)	12:25/12:55	1460.0	1000.0	1460	1006.90	No	1.45
	1 / 8	11OCT2017 (10)	15:53/16:23	1460.0	1000.0	1460	1013.89	No	1.44
	2 / 1	25OCT2017 (24)	12:30/13:00	1460.0	1000.0	1460	1006.90	No	1.45
	2 / 8	01NOV2017 (31)	11:45/12:15	1460.0	1000.0	1460	1006.90	No	1.45
	3 / 1	15NOV2017 (45)	12:03/12:38	1460.0	1000.0	1460	1006.90	No	1.45

Note: Any missing planned dose is due to patient receiving unplanned dose which was not able to be collected in the database.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_drug_f.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.5.3.F
Study Drug Administration - Gemcitabine
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Dose Interrupted/ Reason/Time (Restarted/Time)	BSA
Treatment: Trilaciclib D1D8 + GC Therapy D1D8									
1122001	3 /15	29NOV2017 (59)	12:00/12:30	1140.0	800.0	1140	786.21	No	1.45
	4 / 1	13DEC2017 (73)	12:00/12:30	1140.0	800.0	1140	786.21	No	1.45
	4 / 8	20DEC2017 (80)	14:30/15:11	1140.0	800.0	1140	786.21	No	1.45
	5 / 1	03JAN2018 (94)	12:12/12:45	1140.0	800.0	1140	786.21	No	1.45
	5 / 8	10JAN2018 (101)	11:55/12:25	1140.0	800.0	1140	786.21	No	1.45
	6 / 1	24JAN2018 (115)	12:50/13:20	1140.0	800.0	1140	786.21	No	1.45
	6 / 8	31JAN2018 (122)	12:48/13:18	1140.0	800.0	1140	786.21	No	1.45
	7 / 1	14FEB2018 (136)	12:45/13:15	1140.0	800.0	1140	786.21	No	1.45
	7 / 8	21FEB2018 (143)	12:30/13:00	1140.0	800.0	1140	786.21	No	1.45
	8 / 1	07MAR2018 (157)	12:45/13:15	1140.0	800.0	1140	786.21	No	1.45
	8 / 8	14MAR2018 (164)	11:50/12:20	1140.0	800.0	1140	786.21	No	1.45
	9 / 1	29MAR2018 (179)	11:10/11:40	1140.0	800.0	1140	786.21	No	1.45
	9 / 8	04APR2018 (185)	12:25/12:55	1140.0	800.0	1140	786.21	No	1.45
	10 / 1	18APR2018 (199)	12:19/12:49	1140.0	800.0	1140	786.21	No	1.45
	10 / 8	25APR2018 (206)	12:23/12:53	1140.0	800.0	1140	786.21	No	1.45
	11 / 1	09MAY2018 (220)	13:08/13:38	1140.0	800.0	1140	786.21	No	1.45
	11 / 8	16MAY2018 (227)	12:27/12:57	1140.0	800.0	1140	786.21	No	1.45
	12 / 1	30MAY2018 (241)	14:20/14:50	1140.0	800.0	1140	786.21	No	1.45
	12 / 8	06JUN2018 (248)	14:44/15:14	1140.0	800.0	1140	786.21	No	1.45
	13 / 1	20JUN2018 (262)	13:01/13:33	1140.0	800.0	1140	786.21	No	1.45
	13 / 8	27JUN2018 (269)	13:10/13:40	1140.0	800.0	1140	786.21	No	1.45
	14 / 1	11JUL2018 (283)	11:21/11:51	1140.0	800.0	1140	786.21	No	1.45
	14 / 8	18JUL2018 (290)	12:45/13:15	1140.0	800.0	1140	786.21	No	1.45
	15 / 1	01AUG2018 (304)	13:36/14:04	1140.0	800.0	1140	786.21	No	1.45
	15 / 8	08AUG2018 (311)	15:00/15:30	1140.0	800.0	1140	786.21	No	1.45
	16 / 1	22AUG2018 (325)	13:25/13:55	1140.0	800.0	1140	786.21	No	1.45
	16 / 8	29AUG2018 (332)	14:53/15:24	1140.0	800.0	1140	786.21	No	1.45
	17 / 1	12SEP2018 (346)	12:17/12:47	1140.0	800.0	1140	786.21	No	1.45

Note: Any missing planned dose is due to patient receiving unplanned dose which was not able to be collected in the database.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_drug_f.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.5.3.F
Study Drug Administration - Gemcitabine
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Dose Interrupted/ Reason/Time (Restarted/Time)	BSA
Treatment: Trilaciclib D1D8 + GC Therapy D1D8									
1122001	17 / 8	19SEP2018 (353)	15:30/16:00	1140.0	800.0	1140	786.21	No	1.45
	18 / 1	03OCT2018 (367)	12:02/12:32	1140.0	800.0	1140	786.21	No	1.45
	18 / 8	10OCT2018 (374)	12:38/13:08	1140.0	800.0	1140	786.21	No	1.45
	19 / 1	24OCT2018 (388)	13:04/13:34	1140.0	800.0	1140	786.21	No	1.45
	19 / 8	31OCT2018 (395)	12:20/12:50	1140.0	800.0	1140	786.21	No	1.45
	20 / 1	14NOV2018 (409)	12:00/12:30	1140.0	800.0	1140	786.21	No	1.45
	20 / 8	21NOV2018 (416)	14:15/14:45	1140.0	800.0	1140	786.21	No	1.45
	21 / 1	05DEC2018 (430)	12:30/13:00	1140.0	800.0	1140	786.21	No	1.45
	21 / 8	12DEC2018 (437)	14:54/15:24	1140.0	800.0	1140	786.21	No	1.45
	22 / 1	26DEC2018 (451)	12:50/13:20	1140.0	800.0	1140	786.21	No	1.45
	22 / 8	02JAN2019 (458)	15:01/15:31	1140.0	800.0	1140	786.21	No	1.45
	23 / 1	16JAN2019 (472)	13:58/14:28	1140.0	800.0	1140	786.21	No	1.45
	23 / 8	23JAN2019 (479)	11:20/11:50	1140.0	800.0	1140	786.21	No	1.45
	24 / 1	06FEB2019 (493)	13:48/14:18	1140.0	800.0	1140	786.21	No	1.45
	24 / 8	13FEB2019 (500)	12:25/12:55	1140.0	800.0	1140	786.21	No	1.45
	25 / 1	27FEB2019 (514)	13:18/13:48	1140.0	800.0	1140	786.21	No	1.45
	25 / 8	06MAR2019 (521)	12:44/13:14	1140.0	800.0	1140	786.21	No	1.45
	26 / 1	20MAR2019 (535)	11:28/11:58	1140.0	800.0	1140	786.21	No	1.45
	26 / 8	27MAR2019 (542)	11:16/11:46	1140.0	800.0	1140	786.21	No	1.45
	28 / 1	01MAY2019 (577)	13:10/13:40	1140.0	800.0	1140	786.21	No	1.45
	28 / 8	08MAY2019 (584)	13:32/14:02	1140.0	800.0	1140	786.21	No	1.45
	29 / 1	22MAY2019 (598)	12:30/13:00	1140.0	800.0	1140	786.21	No	1.45
	29 / 8	29MAY2019 (605)	13:10/13:40	1140.0	800.0	1140	797.20	No	1.43
	30 / 1	12JUN2019 (619)	12:07/12:37	1140.0	800.0	1140	786.21	No	1.45
	30 / 8	19JUN2019 (626)	12:22/12:52	1140.0	800.0	1140	786.21	No	1.45
	31 / 1	10JUL2019 (647)	12:50/13:20	1140.0	800.0	1140	786.21	No	1.45
	31 / 8	17JUL2019 (654)	13:58/14:28	1140.0	800.0	1140	797.20	No	1.43
	32 / 1	07AUG2019 (675)	13:35/14:05	1140.0	800.0	1140	786.21	No	1.45

Note: Any missing planned dose is due to patient receiving unplanned dose which was not able to be collected in the database.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_drug_f.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.5.3.F
Study Drug Administration - Gemcitabine
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Cycle/ Day	Date of Dosing (Study Day)	Start/End Time of Infusion	Planned Dose (mg)	Planned Dose (mg/m^2)	Actual Dose (mg)	Derived Dose (mg/m^2)	Dose Interrupted/ Reason/Time (Restarted/Time)	BSA
Treatment: Trilaciclib D1D8 + GC Therapy D1D8									
1122001	33 / 1	21AUG2019 (689)	12:08/12:38	1140.0	800.0	1140	786.21	No	1.45
	33 / 8	28AUG2019 (696)	12:35/13:05	1140.0	800.0	1140	786.21	No	1.45

Note: Any missing planned dose is due to patient receiving unplanned dose which was not able to be collected in the database.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_drug_f.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.5.4.F
Total Exposure - Trilaciclib
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Duration of Exposure (weeks)	Number of Cycles Dosed	Cumulative Actual Dose (mg/m^2)	Dose Intensity (mg/m^2/week)	Relative Dose (%)	Relative Dose Intensity (%)	Number of Dose Interruptions
Treatment: Trilaciclib D1D8 + GC Therapy D1D8							
1111003	623	29	12245.09	137.6	88.0	86.0	0
1122001	707	32	15122.76	149.7	98.5	93.6	0

Listing 16.2.5.5.F
Total Exposure - Carboplatin
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Duration of Exposure (weeks)	Number of Cycles Dosed	Cumulative Actual Dose (AUC)	Dose Intensity (AUC/week)	Relative Dose (%)	Relative Dose Intensity (%)	Number of Doses Reduced	Number of Dose Interruptions
Treatment: Trilaciclib D1D8 + GC Therapy D1D8								
1111003	623	29	67.00	0.8	57.8	56.5	2	0
1122001	707	32	102.50	1.0	80.1	76.1	1	0

Listing 16.2.5.6.F
Total Exposure - Gemcitabine
Safety analysis set (Cumulative data for subjects 1111003 and 1122001 who were still on study drug after 28JUN2019)

Subject Number	Duration of Exposure (weeks)	Number of Cycles Dosed	Cumulative Actual Dose (mg/m^2)	Dose Intensity (mg/m^2/week)	Relative Dose (%)	Relative Dose Intensity (%)	Number of Doses Reduced	Number of Dose Interruptions
Treatment: Trilaciclib D1D8 + GC Therapy D1D8								
1111003	623	29	47304.35	531.5	81.6	79.7	1	0
1122001	707	32	50663.65	501.6	79.2	75.2	1	0

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]				Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA	Other [c]		
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Gastrointestinal disorders Vomiting VOMITING (55)	13JUL2019 (573)	15JUL2019 (575)	No/1	1	2	2	7	1	1	1	RECOVERED/ RESOLVED	Yes/ No
	Vascular disorders Hypertension HYPERTENSION (54)	15JUL2019 (575)	22JUL2019 (582)	No/3	1	2	2	7	1	1	1	RECOVERED/ RESOLVED	Yes/ No
	General disorders and administration site conditions Asthenia WEAKNESS (56)	22JUL2019 (582)	17SEP2019 (639)	No/1	1	3	3	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No
	General disorders and administration site conditions Pyrexia FEVER (58)	26JUL2019 (586)	29JUL2019 (589)	No/1	1	2	2	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No
	Blood and lymphatic system disorders Anaemia ANEMIA (59)	27JUL2019 (587)	29JUL2019 (589)	No/3	1	3	3	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No

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[b] 1 = DOSE NOT CHANGED; 2 = DOSE REDUCED; 3 = DRUG INTERRUPTED; 4 = PERMANENT DISCONTINUATION; 5 = DOSE SKIPPED; 6 = DOSE DELAYED; 7 = NOT APPLICABLE; 8 = UNKNOWN.
[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]				Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA	Other [c]		
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	General disorders and administration site conditions Chills CHILLS (57)	27JUL2019 (587)	29JUL2019 (589)	No/1	1	2	2	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No
	Investigations Platelet count decreased PLATELET COUNT DECREASED (62)	27JUL2019 (587)	12AUG2019 (603)	No/1	1	3	3	7	5	5	4	RECOVERED/ RESOLVED	Yes/ No
	General disorders and administration site conditions Fatigue FATIGUE WORSENING (61)	27JUL2019 (587)	01OCT2019 (653)	No/3	1	2	2	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No

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[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class / Preferred Term / Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]			Other [c]	Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA			
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Infections and infestations / Urinary tract infection / URINARY TRACT INFECTION (45)	27JUL2019 (587)	Ongoing	No/1	1	3	3	7	5	5	1	NOT RECOVERED/ NOT RESOLVED	Yes/ No
	Blood and lymphatic system disorders / Anaemia / ANEMIA (60)	29JUL2019 (589)	16AUG2019 (607)	No/2	1	3	3	7	5	5	4	RECOVERED/ RESOLVED	Yes/ No
	Infections and infestations / Upper respiratory tract infection / UPPER RESPIRATORY INFECTION (71)	29JUL2019 (589)	26AUG2019 (617)	No/2	1	3	3	7	5	5	1	RECOVERED/ RESOLVED	Yes/ No
	Respiratory, thoracic and mediastinal disorders / Dyspnoea / DYSPNEA (72)	29JUL2019 (589)	02SEP2019 (624)	No/2	1	2	2	7	5	5	1	RECOVERED/ RESOLVED	Yes/ No

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[b] 1 = DOSE NOT CHANGED; 2 = DOSE REDUCED; 3 = DRUG INTERRUPTED; 4 = PERMANENT DISCONTINUATION; 5 = DOSE SKIPPED; 6 = DOSE DELAYED; 7 = NOT APPLICABLE; 8 = UNKNOWN.
[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]				Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA	Other [c]		
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Gastrointestinal disorders Diarrhoea DIARRHEA INTERMITTENT (73)	09AUG2019 (600)	Ongoing	No/1	1	2	2	7	1	1	4	NOT RECOVERED/ NOT RESOLVED	Yes/ No
	Musculoskeletal and connective tissue disorders Back pain BACK PAIN (75)	13AUG2019 (604)	17AUG2019 (608)	No/2	1	2	2	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No
	Gastrointestinal disorders Abdominal pain ABDOMINAL PAIN (74)	13AUG2019 (604)	04SEP2019 (626)	No/2	1	2	2	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No
	Blood and lymphatic system disorders Anaemia ANEMIA (51)	16AUG2019 (607)	17AUG2019 (608)	No/3	1	3	3	7	5	5	3	RECOVERED/ RESOLVED	Yes/ No

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[b] 1 = DOSE NOT CHANGED; 2 = DOSE REDUCED; 3 = DRUG INTERRUPTED; 4 = PERMANENT DISCONTINUATION; 5 = DOSE SKIPPED; 6 = DOSE DELAYED; 7 = NOT APPLICABLE; 8 = UNKNOWN.
[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]			Other [c]	Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA			
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Renal and urinary disorders Haematuria HEMATURIA (48)	16AUG2019 (607)	20AUG2019 (611)	Yes/3	1	2	2	7	5	5	5: CONCOMITANT MEDICATION AND CONCOMITANT PROCEDURE	RECOVERED/ RESOLVED	Yes/ No
	Renal and urinary disorders Nephrolithiasis RENAL CALCULI BILATERAL NON OBSTRUCTION (76)	16AUG2019 (607)	28AUG2019 (619)	No/3	1	2	2	7	1	1	1	RECOVERED/ RESOLVED	Yes/ No
	Respiratory, thoracic and mediastinal disorders Pleural effusion PLEURAL EFFUSION BILATERAL (50)	16AUG2019 (607)	04SEP2019 (626)	No/3	1	2	2	7	1	1	2	NOT RECOVERED/ NOT RESOLVED	Yes/ No
	Blood and lymphatic system disorders Anaemia ANEMIA (64)	17AUG2019 (608)	17AUG2019 (608)	No/1	1	3	3	1	1	1	4	RECOVERED/ RESOLVED	Yes/ No

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[b] 1 = DOSE NOT CHANGED; 2 = DOSE REDUCED; 3 = DRUG INTERRUPTED; 4 = PERMANENT DISCONTINUATION; 5 = DOSE SKIPPED; 6 = DOSE DELAYED; 7 = NOT APPLICABLE; 8 = UNKNOWN.
[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class / Preferred Term / Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]				Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA	Other [c]		
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Investigations / Platelet count decreased / PLATELET COUNT DECREASED (77)	17AUG2019 (608)	18AUG2019 (609)	No/2	1	3	3	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No
	Investigations / Platelet count decreased / PLATELET COUNT DECREASED (78)	18AUG2019 (609)	19AUG2019 (610)	No/3	1	3	3	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No
	Metabolism and nutrition disorders / Hypocalcaemia / HYPOCALCEMIA (91)	18AUG2019 (609)	20AUG2019 (611)	No/1	1	1	1	7	1	1	1	RECOVERED/ RESOLVED	Yes/ No
	Blood and lymphatic system disorders / Anaemia / ANEMIA (65)	18AUG2019 (609)	27AUG2019 (618)	No/2	1	3	3	7	1	1	4	RECOVERED/ RESOLVED	Yes/ No

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[b] 1 = DOSE NOT CHANGED; 2 = DOSE REDUCED; 3 = DRUG INTERRUPTED; 4 = PERMANENT DISCONTINUATION; 5 = DOSE SKIPPED; 6 = DOSE DELAYED; 7 = NOT APPLICABLE; 8 = UNKNOWN.
[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]				Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA	Other [c]		
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Investigations Platelet count decreased PLATELET COUNT DECREASED (63)	19AUG2019 (610)	26AUG2019 (617)	No/2	1	3	3	7	5	5	4	RECOVERED/ RESOLVED	Yes/ No
	Musculoskeletal and connective tissue disorders Flank pain FLANK PAIN LOWER BACK RADIATES TO LEFT FLANK (79)	23AUG2019 (614)	31AUG2019 (622)	No/2	1	2	2	7	5	5	1	RECOVERED/ RESOLVED	Yes/ No
	Gastrointestinal disorders Vomiting VOMITING (81)	24AUG2019 (615)	24AUG2019 (615)	No/1	1	2	2	7	5	5	4	RECOVERED/ RESOLVED	Yes/ No

[a] 1 = UNRELATED; 2 = UNLIKELY RELATED; 3 = POSSIBLY RELATED; 4 = PROBABLY RELATED; 5 = DEFINITELY RELATED.
[b] 1 = DOSE NOT CHANGED; 2 = DOSE REDUCED; 3 = DRUG INTERRUPTED; 4 = PERMANENT DISCONTINUATION; 5 = DOSE SKIPPED; 6 = DOSE DELAYED; 7 = NOT APPLICABLE; 8 = UNKNOWN.
[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]			Other [c]	Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA			
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Renal and urinary disorders Hydronephrosis URINARY TRACT OBSTRUCTION MILD LEFT HYDRONEPHROSIS (83)	24AUG2019 (615)	26AUG2019 (617)	No/3	1	2	2	7	5	5	1	RECOVERED/ RESOLVED	Yes/ No
	Cardiac disorders Pericardial effusion PERICARDIAL EFFUSION (80)	24AUG2019 (615)	Ongoing	No/2	1	2	2	7	5	5	4	UNKNOWN	Yes/ No
	Gastrointestinal disorders Diverticulum intestinal COLONIC DIVERTICULOSIS (82)	24AUG2019 (615)	Ongoing	No/1	1	2	2	7	5	5	4	NOT RECOVERED/ NOT RESOLVED	Yes/ No

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[b] 1 = DOSE NOT CHANGED; 2 = DOSE REDUCED; 3 = DRUG INTERRUPTED; 4 = PERMANENT DISCONTINUATION; 5 = DOSE SKIPPED; 6 = DOSE DELAYED; 7 = NOT APPLICABLE; 8 = UNKNOWN.
[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]				Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA	Other [c]		
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Renal and urinary disorders Acute kidney injury ACUTE KIDNEY INJURY (94)	26AUG2019 (617)	31AUG2019 (622)	No/3	1	2	2	7	4	4	1	RECOVERED/ RESOLVED	Yes/ Yes
	Renal and urinary disorders Urinary tract obstruction URINARY TRACT OBSTRUCTION (49)	26AUG2019 (617)	31AUG2019 (622)	Yes/3	1	2	2	7	7	7	2	RECOVERED/ RESOLVED	Yes/ No
	Infections and infestations Pneumonia PNEUMONIA (68)	26AUG2019 (617)	Ongoing	No/2	1	3	3	7	7	7	1	UNKNOWN	Yes/ No
	Skin and subcutaneous tissue disorders Ecchymosis BRUISING ECCHYMOSIS AROUND RIGHT EYE (84)	27AUG2019 (618)		No/1	1	3	3	7	7	7	4	UNKNOWN	Yes/ No

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[b] 1 = DOSE NOT CHANGED; 2 = DOSE REDUCED; 3 = DRUG INTERRUPTED; 4 = PERMANENT DISCONTINUATION; 5 = DOSE SKIPPED; 6 = DOSE DELAYED; 7 = NOT APPLICABLE; 8 = UNKNOWN.
[c] 1 = CONCOMITANT MEDICATION; 2 = CONCOMITANT PROCEDURE; 3 = BLOOD TRANSFUSION; 4 = NONE; 5 = OTHER.
CTCAE = common terminology criteria for adverse events; SAE = serious adverse event; CAB = carboplatin; GEM = Gemcitabine; TRILA = Trilaciclib
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]			Other [c]	Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA			
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Blood and lymphatic system disorders Anaemia ANEMIA (66)	27AUG2019 (618)	30AUG2019 (621)	No/3	1	3	3	7	7	7	3	RECOVERED/ RESOLVED	Yes/ No
	Gastrointestinal disorders Constipation CONSTIPATION (69)	27AUG2019 (618)	04SEP2019 (626)	No/1	1	2	2	7	7	7	1	RECOVERED/ RESOLVED	Yes/ No
	Gastrointestinal disorders Abdominal pain lower ABDOMINAL PAIN INTERMITTENT LEFT LOWER QUADRANT (70)	28AUG2019 (619)	31AUG2019 (622)	No/1	1	2	2	7	7	7	4	RECOVERED/ RESOLVED	Yes/ No
	Renal and urinary disorders Acute kidney injury ACUTE KIDNEY INJURY (86)	29AUG2019 (620)	04SEP2019 (626)	No/2	1	2	2	7	7	7	4	RECOVERED/ RESOLVED	Yes/ No

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Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]			Other [c]	Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA			
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Blood and lymphatic system disorders Anaemia ANEMIA (92)	30AUG2019 (621)	05SEP2019 (627)	No/2	1	3	3	7	7	7	4	RECOVERED/ RESOLVED	Yes/ No
	Musculoskeletal and connective tissue disorders Flank pain FLANK PAIN LEFT (85)	31AUG2019 (622)	16SEP2019 (638)	No/1	1	2	2	7	7	7	4	RECOVERED/ RESOLVED	Yes/ No
	Respiratory, thoracic and mediastinal disorders Dyspnoea DYSPNEA (87)	02SEP2019 (624)	Ongoing	No/3	1	2	2	7	7	7	1	NOT RECOVERED/ NOT RESOLVED	Yes/ No
	Respiratory, thoracic and mediastinal disorders Pleural effusion PLEURAL EFFUSION (52)	04SEP2019 (626)	10SEP2019 (632)	Yes/3	1	3	3	7	7	7	2	RECOVERED/ RESOLVED	Yes/ No

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Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]				Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA	Other [c]		
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Renal and urinary disorders Acute kidney injury ACUTE KIDNEY INJURY (88)	04SEP2019 (626)	Ongoing	No/1	1	2	2	7	7	7	4	NOT RECOVERED/ NOT RESOLVED	Yes/ No
	Respiratory, thoracic and mediastinal disorders Pulmonary oedema PULMONARY EDEMA (96)	04SEP2019 (626)	Ongoing	No/3	1	2	3	7	7	7	1	NOT RECOVERED/ NOT RESOLVED	Yes/ No
	Blood and lymphatic system disorders Anaemia ANEMIA (47)	05SEP2019 (627)	09SEP2019 (631)	No/3	1	3	3	7	7	7	4	RECOVERED/ RESOLVED	Yes/ No
	Blood and lymphatic system disorders Anaemia ANEMIA (67)	09SEP2019 (631)	Ongoing	No/1	1	3	3	7	7	7	4	NOT RECOVERED/ NOT RESOLVED	Yes/ No

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Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]				Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA	Other [c]		
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1111003	Respiratory, thoracic and mediastinal disorders Pleural effusion PLEURAL EFFUSION (95)	10SEP2019 (632)	09DEC2019 (722)	No/3	1	3	3	7	7	7	4	RECOVERED/ RESOLVED	Yes/ No
	Neoplasms benign, malignant and unspecified (incl cysts and polyps) Pelvic neoplasm NEOPLASM BENIGN LUMP ON PELVIC AREA (90)	12SEP2019 (634)		No/1	1	1	1	7	7	7	4	UNKNOWN	No/ No
1122001	General disorders and administration site conditions Axillary pain RIGHT AXILLA PAIN (11)	28AUG2019 (696)	Ongoing	No/1	1	1	1	1	1	1	4	NOT RECOVERED/ NOT RESOLVED	Yes/ No

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Listing 16.2.7.1.I
Adverse Events
All enrolled patients (incremental data after 28JUN2019)

Subject Number	System Organ Class Preferred Term Verbatim Term (AE Number)	Start Date/Time (Study Day)	Resolution Date/Time (Study Day)	SAE/ CTCAE Grade	Relationship [a]			Action Taken [b]				Outcome	TEAE/ Disc. Study
					CAB	GEM	TRILA	CAB	GEM	TRILA	Other [c]		
Treatment: Trilaciclib D1D8 + GC Therapy D1D8													
1122001	Blood and lymphatic system disorders Thrombocytopenia THROMBOCYTOPENIA (12)	04SEP2019 (703)	11SEP2019 (710)	No/3	5	5	1	7	7	7	4	RECOVERED/ RESOLVED	Yes/ No
1131011	Respiratory, thoracic and mediastinal disorders Nasal congestion NASAL CONGESTION (75)	09JUL2019 (520)	Ongoing	No/1	1	1	1	1	1	1	4	NOT RECOVERED/ NOT RESOLVED	No/ No

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Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_ae_inc.sas, Date/time of run: 11SEP2020:17:32

Listing 16.2.13.4.1
Disease Progression (Derived Assessments) or Death
All enrolled patients

Subject Number	Overall Response (RECIST)	Overall Response (Unconfirmed)	Date to First Achieve Confirmed CR or PR	Duration of Response (months)	Progression Free Survival (months)	Progression Free Survival, with Clinical Progression (months)	Overall Survival (months)
Screen Failure							
1017001							
1110001							
1110002							
1111006							
1113002							
1114004							
1116002							
1118004							
1120003							
1121003							
1123002							
1123003							
1124001							
1125004							
1126001							
1127002							
1129002							
1129003							
1129004							
1130002							
1131002							
1131003							
1131007							
1131008							
1131009							
1131012							
1133003							

Note: * indicates a censored event.
Source: P:\G1 Therapeutics\G1T28-04\Programs\Analysis\Production\Listings\l_prog.sas, Date/time of run: 11SEP2020:17:33

Listing 16.2.13.4.1
Disease Progression (Derived Assessments) or Death
All enrolled patients

Subject Number	Overall Response (RECIST)	Overall Response (Unconfirmed)	Date to First Achieve Confirmed CR or PR	Duration of Response (months)	Progression Free Survival (months)	Progression Free Survival, with Clinical Progression (months)	Overall Survival (months)
Screen Failure							
1139001							
1145006							
1148002							
1154001							
1154003							
1155002							
1156006							
1162001							
1163003							
1163004							
1163007							
1165002							
1171001							
Treatment: GC Therapy D1D8							
1017002	SD	SD			5.4	5.4	12.8
1110003					0.0*	0.0*	0.1*
1111005	PR	PR	14MAR2018	7.5	9.2	9.2	16.0
1112007	PR	PR	16APR2018	2.2*	3.8*	6.7	18.5
1113003	PR	PR	24NOV2017	1.4*	3.3*	3.5	18.8
1114001					0.0*	0.0*	0.1*
1114002	SD	SD			5.2*	5.2*	6.1*
1114003	PD	PD			1.3	1.3	2.8
1114005	SD	SD			8.3	5.2	8.3
1116004	PD	PD			1.4	1.4	4.8
1117001	PR	PR	12MAR2018	4.3*	6.4*	6.4*	13.9

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Listing 16.2.13.4.1
Disease Progression (Derived Assessments) or Death
All enrolled patients

Subject Number	Overall Response (RECIST)	Overall Response (Unconfirmed)	Date to First Achieve Confirmed CR or PR	Duration of Response (months)	Progression Free Survival (months)	Progression Free Survival, with Clinical Progression (months)	Overall Survival (months)
Treatment: GC Therapy D1D8							
1117005	PD	PD			2.2	2.2	9.9
1121002	SD	SD			1.9	1.9	8.4*
1123001					0.0*	0.0*	0.1*
1123004	SD	SD			1.9*	1.5	4.2
1123005	PR	PR	08NOV2017	7.8	9.2	9.2	25.0
1125006	PD	PD			2.0	2.0	6.3
1128001	SD	Unconfirmed PR			3.3	3.3	5.4
1129001					0.0*	0.0*	1.0*
1131005	SD	SD			5.7	5.7	5.8
1131006	PD	PD			1.2	1.2	3.8
1131013					17.8	17.8	17.8
1131015					11.9*	11.9*	24.1*
1131016					0.0*	0.0*	0.1*
1133001	SD	SD			4.8	4.8	10.5
1133004	PD	PD			0.2	0.2	0.3
1137001					6.5*	10.6	15.6
1145001	SD	SD			2.4*	2.3	7.5
1148005	SD	SD			5.4	4.8	12.6
1154002					3.4*	3.4*	9.7
1156001	PR	PR	14FEB2018	7.2*	8.9*	8.9*	25.7*
1156007					0.1	0.1	0.1
1163002	SD	SD			9.9	9.9	13.8
1163006	PR	PR	31MAY2018	16.7	18.8	18.8	18.8
Treatment: G1T28 D1D8 + GC Therapy D1D8							
1111001	SD	SD			2.1*	2.1*	13.0

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Listing 16.2.13.4.1
Disease Progression (Derived Assessments) or Death
All enrolled patients

Subject Number	Overall Response (RECIST)	Overall Response (Unconfirmed)	Date to First Achieve Confirmed CR or PR	Duration of Response (months)	Progression Free Survival (months)	Progression Free Survival, with Clinical Progression (months)	Overall Survival (months)
Treatment: G1T28 D1D8 + GC Therapy D1D8							
1111003	PR	PR	12FEB2018	23.7*	25.6*	25.6*	26.2*
1112002	PR	PR	17APR2017	17.8	20.1	16.0	20.1
1112004	SD	SD			1.5*	1.5*	2.6*
1113001	SD	SD			8.8	8.8	31.5*
1113004	PR	PR	26DEC2017	4.8	6.2	6.0	6.4*
1117003	SD	SD			9.4	9.4	9.4
1117004					4.3	4.3	7.1
1121001	PR	PR	21JUN2017	1.5*	2.7*	2.7*	33.6*
1122001	PR	PR	11APR2018	17.8	24.1	23.7	29.1*
1124002					0.0*	1.6	4.7
1125001	PR	PR	26OCT2017	9.3	11.9	11.9	17.4*
1125007					1.3	1.3	1.3
1125008	PR	PR	25SEP2018	9.5	14.0	14.0	14.0
1126003	PD	PD			1.3	1.3	10.2
1126004	PD	PD			1.2	1.2	4.3
1127001	PD	PD			1.2	1.2	29.0*
1129005	SD	SD			4.2*	4.2*	28.1*
1131001	PD	PD			0.5	0.5	3.1
1131011	PR	PR	08JUN2018	6.3	10.4	10.4	25.0*
1131014	PR	PR	07MAY2018	7.6	9.7	9.7	19.6
1133002	SD	SD			11.3	11.3	28.5*
1133005					0.0*	0.0*	3.1*
1137002	PD	PD			2.1	2.1	3.4
1141001	PR	PR	16OCT2017	2.7*	4.0*	4.0*	29.6*
1145002	PR	PR	14MAY2018	4.4*	6.1*	6.1*	7.2*
1145005	PR	PR	05JUL2018	2.3*	4.0*	4.0*	5.5*
1148004	SD	Unconfirmed PR			4.0*	4.0	5.1

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Listing 16.2.13.4.1
Disease Progression (Derived Assessments) or Death
All enrolled patients

Subject Number	Overall Response (RECIST)	Overall Response (Unconfirmed)	Date to First Achieve Confirmed CR or PR	Duration of Response (months)	Progression Free Survival (months)	Progression Free Survival, with Clinical Progression (months)	Overall Survival (months)
Treatment: G1T28 D1D8 + GC Therapy D1D8							
1156002	SD	SD			6.1	6.1	6.4*
1163001	SD	SD			7.9	7.9	26.8*
1163005	PR	PR	26MAR2018	12.5	15.5	15.5	25.3*
1165001	PR	PR	19JUL2017	11.5	13.0	13.0	32.8*
1166001	PR	PR	11MAY2018	3.2	5.3	5.3	22.9*
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9							
1111002	PD	PD			1.0	1.0	8.7
1111004					0.0*	0.0*	17.7
1112001	SD	Unconfirmed PR			3.4*	9.0	32.7
1112006					1.2	1.2	3.9
1113005	PR	PR	27APR2018	7.7*	11.5*	11.5*	25.5*
1116001	PR	PR	07DEC2017	5.9	7.3	7.3	28.0*
1116003	SD	SD			2.1*	2.1*	13.1
1117002					15.6	15.6	15.6
1117006	SD	SD			6.4	6.4	19.4
1118001	PD	PD			1.2	1.2	6.0
1118002	PR	PR	18AUG2017	9.6	10.9	10.9	31.9*
1118003	SD	SD			2.9*	2.9*	12.9
1118005	PR	PR	22FEB2018	4.2	6.2	6.2	7.9*
1120001	SD	SD			2.7	2.7	4.5
1120002	SD	Unconfirmed PR			2.1*	2.1*	15.3
1122002	PR	PR	04DEC2017	5.5*	6.7*	6.7*	27.9*
1122003	SD	SD			3.9	1.9	3.9
1125002	SD	Unconfirmed PR			3.9*	3.9	15.3
1125003	PR	PR	26JAN2018	3.1	7.1	7.1	7.1

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Listing 16.2.13.4.1
Disease Progression (Derived Assessments) or Death
All enrolled patients

Subject Number	Overall Response (RECIST)	Overall Response (Unconfirmed)	Date to First Achieve Confirmed CR or PR	Duration of Response (months)	Progression Free Survival (months)	Progression Free Survival, with Clinical Progression (months)	Overall Survival (months)
Treatment: G1T28 D1_2D8_9 + GC Therapy D2D9							
1125005	SD	SD			1.9*	1.9	6.2
1126002	NE	NE			1.1*	6.9	33.7*
1128002					4.0*	4.0*	22.3
1130001	PR	PR	28DEC2017	12.6	14.6	14.6	28.4*
1131004	SD	SD			4.8*	4.8*	19.0*
1131010	SD	Unconfirmed PR			6.5	6.5	6.7*
1145003	PR	PR	25MAY2018	7.9*	9.7*	9.7*	22.5*
1145004	PD	PD			3.4	3.4	3.5*
1148001	PR	PR	12JUN2019	6.1*	26.2*	26.2*	27.7*
1148003	SD	SD			9.0	9.0	17.8
1155001	PR	PR	05APR2018	1.4*	6.2*	6.2*	6.7*
1155003	SD	Unconfirmed PR			5.5*	5.5*	5.7*
1156003					3.8*	3.8*	8.8
1156004	PR	PR	03APR2018	12.0	13.9	13.9	23.7*
1156005	SD	Unconfirmed PR			5.9	5.9	7.5
1164001	PR	PR	30MAY2018	9.6	12.9	12.9	19.8

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5. SIGNATURES INVESTIGATORS

COORDINATING INVESTIGATOR AND SPONSOR'S RESPONSIBLE MEDICAL OFFICER SIGNATURES

STUDY TITLE:	Phase 2 Study of the Safety, Efficacy, and Pharmacokinetics of G1T28 in Patients with Metastatic Triple Negative Breast Cancer Receiving Gemcitabine and Carboplatin Chemotherapy
STUDY AUTHOR(S):	Janet Horton, MD, MHSc G1 Therapeutics
	Joyce Antal, MS G1 Therapeutics
	Erica Allen, PhD EAllen Pharmaceutical Services

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

COORDINATING INVESTIGATOR:

Antoinette Tan, MD	Antoinette Tan	12/9/2020
Levine Cancer Institute	Signature	Date

SPONSOR'S RESPONSIBLE MEDICAL OFFICER:

Andy Beelen, MD	DocuSigned by: Andy Beelen	
VP Clinical Development, G1 Therapeutics	Signature Print Name: Andy Beelen Signing Reason: I approve this document Signing Time: 09-Dec-2020 | 3:47:59 AM PST 0D03AE93D6C341A3B9C652797C39CC83	Date