



Clinical trial results:

A Phase 2, Randomized, Open-label, 3-arm Study of Relacorilant in Combination with Nab-Paclitaxel for Patients with Platinum Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.

Summary

EudraCT number	2018-004186-14
Trial protocol	BE ES IT
Global end of trial date	12 July 2023

Results information

Result version number	v1 (current)
This version publication date	23 January 2026
First version publication date	23 January 2026

Trial information

Trial identification

Sponsor protocol code	CORT125134-552
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03776812
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Corcept Therapeutics
Sponsor organisation address	101 Redwood Shores Parkway, Redwood City, United States, 94065
Public contact	Corcept Therapeutics, Medical Director, +1 650-327-3270, info@corcept.com
Scientific contact	Corcept Therapeutics, Medical Director, +1 650-327-3270, info@corcept.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 July 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	12 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The goal of this study is to evaluate the efficacy of relacorilant either administered daily (continuous) or on the day prior, the day of, and the day after chemotherapy (intermittent) in combination with nab-paclitaxel in the treatment of platinum-resistant ovarian, fallopian tube, or primary peritoneal cancers compared with nab-paclitaxel alone.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 April 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 31
Country: Number of subjects enrolled	Belgium: 25
Country: Number of subjects enrolled	Italy: 49
Country: Number of subjects enrolled	United States: 60
Country: Number of subjects enrolled	Canada: 13
Worldwide total number of subjects	178
EEA total number of subjects	105

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	116
From 65 to 84 years	62
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subject Disposition is reported for the Intent-to-Treat (ITT) Population: all enrolled and randomized patients.

Pre-assignment

Screening details:

A total of 178 patients were enrolled in the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A: Continuous Relacorilant Dosing

Arm description:

Patients will receive relacorilant 100 mg (titrated up to 150 mg after Cycle 1 or 2) once daily in combination with nab-paclitaxel 80 mg/m², on Days 1, 8, and 15 of each 28-day cycle.

Arm type	Experimental
Investigational medicinal product name	Relacorilant
Investigational medicinal product code	
Other name	CORT125134
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Relacorilant is supplied as capsules for oral dosing.

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	Abraxane
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nab-paclitaxel is administered as IV infusion over 30-40 minutes.

Arm title	Arm B: Intermittent Relacorilant Dosing
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Arm description:

Patients will receive relacorilant 150 mg on the day before (excluding Cycle 1, Day -1), the day of, and the day after nab-paclitaxel, in combination with nab-paclitaxel 80 mg/m², on Days 1, 8, and 15 of each 28-day cycle.

Arm type	Experimental
Investigational medicinal product name	Relacorilant
Investigational medicinal product code	
Other name	CORT125134
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Relacorilant is supplied as capsules for oral dosing.

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	Abraxane
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use
Dosage and administration details:	
Nab-paclitaxel is administered as IV infusion over 30-40 minutes.	
Arm title	Arm C: Nab-Paclitaxel Comparator

Arm description:

Patients will receive nab-paclitaxel 100 mg/m² on Days 1, 8, and 15 of each 28-day cycle. Patients initially in Arm C who choose to cross over after disease progression will receive relacorilant 100 mg (titrated up to 150 mg) in combination with nab-paclitaxel 80 mg/m² on Days 1, 8, and 15 of each 28-day cycle after cross over.

Arm type	Active comparator
Investigational medicinal product name	Relacorilant
Investigational medicinal product code	
Other name	CORT125134
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Relacorilant is supplied as capsules for oral dosing.

Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	Abraxane
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nab-paclitaxel is administered as IV infusion over 30-40 minutes.

Number of subjects in period 1	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab-Paclitaxel Comparator
Started	58	60	60
Entered Crossover	0	0	28
Completed	0	0	0
Not completed	58	60	60
Consent withdrawn by subject	1	7	2
Did not enter long-term follow-up	3	3	2
Death	53	49	56
Lost to follow-up	1	1	-

Baseline characteristics

Reporting groups

Reporting group title	Arm A: Continuous Relacorilant Dosing
Reporting group description: Patients will receive relacorilant 100 mg (titrated up to 150 mg after Cycle 1 or 2) once daily in combination with nab-paclitaxel 80 mg/m ² , on Days 1, 8, and 15 of each 28-day cycle.	
Reporting group title	Arm B: Intermittent Relacorilant Dosing
Reporting group description: Patients will receive relacorilant 150 mg on the day before (excluding Cycle 1, Day -1), the day of, and the day after nab-paclitaxel, in combination with nab-paclitaxel 80 mg/m ² , on Days 1, 8, and 15 of each 28-day cycle.	
Reporting group title	Arm C: Nab-Paclitaxel Comparator
Reporting group description: Patients will receive nab-paclitaxel 100 mg/m ² on Days 1, 8, and 15 of each 28-day cycle. Patients initially in Arm C who choose to cross over after disease progression will receive relacorilant 100 mg (titrated up to 150 mg) in combination with nab-paclitaxel 80 mg/m ² on Days 1, 8, and 15 of each 28-day cycle after cross over.	

Reporting group values	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab-Paclitaxel Comparator
Number of subjects	58	60	60
Age categorical Units: Subjects			
Adults (18-64 years)	36	38	42
From 65 to 84 years	22	22	18
Age continuous Units: years			
arithmetic mean	60.6	60.3	61.8
standard deviation	± 8.8	± 9.7	± 8.8
Gender categorical Units: Subjects			
Female	58	60	60
Male	0	0	0

Reporting group values	Total		
Number of subjects	178		
Age categorical Units: Subjects			
Adults (18-64 years)	116		
From 65 to 84 years	62		
Age continuous Units: years			
arithmetic mean	-		
standard deviation	-		
Gender categorical Units: Subjects			
Female	178		
Male	0		

End points

End points reporting groups

Reporting group title	Arm A: Continuous Relacorilant Dosing
Reporting group description: Patients will receive relacorilant 100 mg (titrated up to 150 mg after Cycle 1 or 2) once daily in combination with nab-paclitaxel 80 mg/m ² , on Days 1, 8, and 15 of each 28-day cycle.	
Reporting group title	Arm B: Intermittent Relacorilant Dosing
Reporting group description: Patients will receive relacorilant 150 mg on the day before (excluding Cycle 1, Day -1), the day of, and the day after nab-paclitaxel, in combination with nab-paclitaxel 80 mg/m ² , on Days 1, 8, and 15 of each 28-day cycle.	
Reporting group title	Arm C: Nab-Paclitaxel Comparator
Reporting group description: Patients will receive nab-paclitaxel 100 mg/m ² on Days 1, 8, and 15 of each 28-day cycle. Patients initially in Arm C who choose to cross over after disease progression will receive relacorilant 100 mg (titrated up to 150 mg) in combination with nab-paclitaxel 80 mg/m ² on Days 1, 8, and 15 of each 28-day cycle after cross over.	
Subject analysis set title	Crossover Patients
Subject analysis set type	Intention-to-treat
Subject analysis set description: Patients initially in the Nab-paclitaxel Comparator Arm (Arm C) who choose to cross over after disease progression will receive relacorilant, 100 mg in combination with nab-paclitaxel, 80 mg/m ² . Relacorilant is supplied as capsules for oral dosing. Nab-paclitaxel is administered as IV infusion over 30-40 minutes on Days 1, 8, and 15 of each 28-day cycle.	

Primary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)
End point description: To assess time from randomization until the date of first documented progressive disease (PD) by RECIST v1.1 (as determined by the Investigator at the local site), or death due to any cause, whichever occurs first. The population analyzed is intent-to-treat (ITT), including all randomized patients.	
End point type	Primary
End point timeframe: Baseline and up to 15 months	

End point values	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab- Paclitaxel Comparator	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	60	60	
Units: Months				
median (confidence interval 95%)	5.29 (3.84 to 5.55)	5.55 (3.68 to 7.20)	3.76 (3.52 to 5.36)	

Statistical analyses

Statistical analysis title	Hazard Ratio: Arm A versus Arm C
Comparison groups	Arm A: Continuous Relacorilant Dosing v Arm C: Nab-Paclitaxel Comparator
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3293
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56
upper limit	1.22

Statistical analysis title	Hazard Ratio: Arm B versus Arm C
Comparison groups	Arm C: Nab-Paclitaxel Comparator v Arm B: Intermittent Relacorilant Dosing
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0384
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.44
upper limit	0.98

Secondary: Objective Response Rate (ORR)	
End point title	Objective Response Rate (ORR)
End point description: To assess the proportion of patients with measurable disease at Baseline who attain complete response (CR) or partial response (PR) by RECIST v1.1 (confirmation not required). The population analyzed is the ITT population with measurable disease at Baseline.	
End point type	Secondary
End point timeframe: Baseline and up to 15 months	

End point values	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab- Paclitaxel Comparator	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	54	56	53	
Units: Percentage of patients				
number (not applicable)	35.19	35.71	35.85	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)
End point description: To assess the time from when response (CR or PR) was first documented to the first objectively documented PD or death (whichever occurs first). The population analyzed is the ITT population with measurable disease at Baseline and who attain CR or PR by RECIST v1.1.	
End point type	Secondary
End point timeframe: From first documented response up to 12 months	

End point values	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab- Paclitaxel Comparator	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	20	19	
Units: Months				
median (confidence interval 95%)	3.79 (2.33 to 5.55)	5.55 (3.75 to 5.88)	3.65 (2.89 to 5.09)	

Statistical analyses

No statistical analyses for this end point

Secondary: Cancer Antigen 125 (CA-125) Response According to Gynecological Cancer Intergroup Criteria (GCIG)

End point title	Cancer Antigen 125 (CA-125) Response According to Gynecological Cancer Intergroup Criteria (GCIG)
End point description: To assess the overall CA-125 response per GCIG criteria. Response was defined as $\geq 50\%$ reduction in CA-125 from a pre-treatment sample. Patients whose CA-125 levels fall within the reference range are classified as complete responders. The population analyzed is the ITT population with an initial CA-125 level \geq twice the upper limit of normal (ULN) of the reference range.	
End point type	Secondary

End point timeframe:

Baseline and up to 15 months

End point values	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab- Paclitaxel Comparator	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	53	52	
Units: Percentage of patients				
number (not applicable)	62.75	64.15	53.85	

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR)

End point title	Best Overall Response (BOR)
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End point description:

To assess the best response (CR, PR, stable disease [SD], or PD) recorded from the date of randomization until PD/recurrence (or death). The population analyzed is the ITT population with measurable disease at Baseline.

End point type	Secondary
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End point timeframe:

Baseline and up to 15 months

End point values	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab- Paclitaxel Comparator	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	54	56	53	
Units: Percentage of patients				
number (not applicable)				
Complete response	7.41	1.79	3.77	
Partial response	27.78	33.93	32.08	
Stable disease	42.59	35.71	39.62	
Progressive disease	16.67	25	22.64	
Not evaluable	5.56	3.57	1.89	

Statistical analyses

No statistical analyses for this end point

Secondary: PFS Rate at 6 and 12 Months

End point title	PFS Rate at 6 and 12 Months
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End point description:

To assess the proportion of patients who have not progressed according to RECIST v1.1 criteria at 6 and 12 months. The population analyzed is the ITT population including all randomized patients. Values are Kaplan-Meier estimates of the patients who are progression-free at the time points specified.

End point type	Secondary
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End point timeframe:

6 and 12 months

End point values	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab- Paclitaxel Comparator	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	60	60	
Units: Proportion of patients				
number (confidence interval 95%)				
6 months	0.26 (0.15 to 0.38)	0.40 (0.28 to 0.53)	0.25 (0.15 to 0.36)	
12 months	0.08 (0.02 to 0.18)	0.11 (0.04 to 0.23)	0.04 (0.01 to 0.12)	

Statistical analyses

No statistical analyses for this end point

Secondary: PFS in Patients who Cross Over to Continuous Treatment at Time of Initial PD

End point title	PFS in Patients who Cross Over to Continuous Treatment at Time of Initial PD
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End point description:

To assess the time from crossover Baseline (initial PD) until the earliest date of subsequent PD by RECIST v1.1, as determined by the Investigator at the local site, or death from any cause, whichever comes first. The population analyzed is the ITT population initially in Arm C: Nab-paclitaxel Comparator, who choose to cross over after disease progression.

End point type	Secondary
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End point timeframe:

Crossover Baseline (Day 50) and up to Day 272

End point values	Crossover Patients			
Subject group type	Subject analysis set			
Number of subjects analysed	27			
Units: Months				
median (confidence interval 95%)	2.10 (1.87 to 2.50)			

Statistical analyses

No statistical analyses for this end point

Secondary: ORR in Patients who Cross Over to Continuous Treatment at Time of Initial PD

End point title	ORR in Patients who Cross Over to Continuous Treatment at Time of Initial PD
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End point description:

To assess the proportion of patients with measurable disease at the crossover Baseline who attain confirmed CR or PR by RECIST v1.1. The population analyzed is the ITT population initially in Arm C: Nab-paclitaxel Comparator, who choose to cross over after disease progression and have measurable disease at the crossover Baseline.

End point type	Secondary
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End point timeframe:

Crossover Baseline (Day 50) and up to Day 272

End point values	Crossover Patients			
Subject group type	Subject analysis set			
Number of subjects analysed	21			
Units: Percentage of patients				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: DOR in Patients who Cross Over to Continuous Treatment at Time of Initial PD

End point title	DOR in Patients who Cross Over to Continuous Treatment at Time of Initial PD
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End point description:

To assess the time from when the first objective response (CR or PR) in the crossover period to the first objectively documented subsequent PD, or death (whichever occurs first). The population analyzed is the ITT population initially in Arm C: Nab-paclitaxel Comparator, who choose to cross over after disease progression, have measurable disease at the crossover Baseline, and attain CR or PR during the crossover period.

End point type	Secondary
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End point timeframe:

From the time of objective response in the crossover period to the time of subsequent PD

End point values	Crossover Patients			
Subject group type	Subject analysis set			
Number of subjects analysed	0 ^[1]			
Units: Months				
median (confidence interval 95%)	(to)			

Notes:

[1] - No crossover patients attained CR or PR, so duration of response could not be analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: BOR in Patients who Cross Over to Continuous Treatment at Time of Initial PD

End point title	BOR in Patients who Cross Over to Continuous Treatment at Time of Initial PD
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End point description:

To assess the best overall response (CR, PR, SD, or PD) recorded in the crossover period. The population analyzed is the ITT population initially in Arm C: Nab-paclitaxel Comparator, who choose to cross over after disease progression and have measurable disease at the crossover Baseline.

End point type	Secondary
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End point timeframe:

Crossover Baseline (Day 50) and up to Day 272

End point values	Crossover Patients			
Subject group type	Subject analysis set			
Number of subjects analysed	21			
Units: Percentage of patients				
number (not applicable)				
Complete response	0			
Partial response	0			
Stable disease	14.29			
Progressive disease	85.71			
Not evaluable	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
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End point description:

To assess the time from randomization to death by any cause. The population analyzed is the ITT population including all randomized patients.

End point type	Secondary
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End point timeframe:

Up to 31 months

End point values	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab- Paclitaxel Comparator	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	60	60	
Units: Months				
median (confidence interval 95%)	11.30 (7.52 to 16.39)	13.90 (11.07 to 18.43)	12.19 (7.72 to 15.28)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response According to Combined RECIST v1.1 + GCIG Criteria

End point title	Overall Response According to Combined RECIST v1.1 + GCIG Criteria
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End point description:

To assess the proportion of patients with measurable disease at Baseline who attain confirmed CR or PR by RECIST v1.1 and GCIG criteria. GCIG response was defined as $\geq 50\%$ reduction in CA-125 from a pre-treatment sample. The population analyzed is ITT Population with an initial CA-125 level \geq twice the ULN of the reference range within 2 weeks before starting treatment.

End point type	Secondary
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End point timeframe:

Baseline and up to 15 months

End point values	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab- Paclitaxel Comparator	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	58	60	60	
Units: Percentage of patients				
number (not applicable)	58.62	60	55	

Statistical analyses

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 39 months

Adverse event reporting additional description:

The safety population included all randomized patients who received ≥ 1 dose of study treatment.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

Reporting group title	Arm A: Continuous Relacorilant Dosing
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Reporting group description:

Patients will receive relacorilant 100 mg (titrated up to 150 mg after Cycle 1 or 2) once daily in combination with nab-paclitaxel 80 mg/m², on Days 1, 8, and 15 of each 28-day cycle.

Reporting group title	Arm B: Intermittent Relacorilant Dosing
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Reporting group description:

Patients will receive relacorilant 150 mg on the day before (excluding Cycle 1, Day -1), the day of, and the day after nab-paclitaxel, in combination with nab-paclitaxel 80 mg/m², on Days 1, 8, and 15 of each 28-day cycle.

Reporting group title	Arm C: Nab-Paclitaxel Comparator
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Reporting group description:

Patients will receive nab-paclitaxel 100 mg/m² on Days 1, 8, and 15 of each 28-day cycle. Patients initially in Arm C who choose to cross over after disease progression will receive relacorilant 100 mg (titrated up to 150 mg) in combination with nab-paclitaxel 80 mg/m² on Days 1, 8, and 15 of each 28-day cycle after cross over.

Serious adverse events	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab-Paclitaxel Comparator
Total subjects affected by serious adverse events			
subjects affected / exposed	30 / 57 (52.63%)	15 / 60 (25.00%)	19 / 60 (31.67%)
number of deaths (all causes)	52	49	56
number of deaths resulting from adverse events	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant pleural effusion			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 57 (0.00%)	2 / 60 (3.33%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	2 / 57 (3.51%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 57 (1.75%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	3 / 57 (5.26%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	2 / 57 (3.51%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Electrocardiogram ST segment elevation			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Gastrointestinal stoma necrosis			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma prolapse			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Monoparesis			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic neurological syndrome			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Syncope			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	3 / 57 (5.26%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	1 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	1 / 57 (1.75%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	2 / 57 (3.51%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	5 / 57 (8.77%)	2 / 60 (3.33%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	2 / 57 (3.51%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	3 / 57 (5.26%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			

subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 57 (3.51%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant ascites			
subjects affected / exposed	1 / 57 (1.75%)	2 / 60 (3.33%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Melanocytic hyperplasia			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hydronephrosis			
subjects affected / exposed	1 / 57 (1.75%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Biliary tract infection			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia pyelonephritis			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 57 (3.51%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Stoma site abscess			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subperiosteal abscess			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	2 / 60 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 57 (1.75%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial diarrhoea			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			

Dehydration			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 57 (0.00%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Arm A: Continuous Relacorilant Dosing	Arm B: Intermittent Relacorilant Dosing	Arm C: Nab-Paclitaxel Comparator
Total subjects affected by non-serious adverse events			
subjects affected / exposed	57 / 57 (100.00%)	59 / 60 (98.33%)	60 / 60 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	3 / 57 (5.26%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences (all)	3	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 57 (10.53%)	5 / 60 (8.33%)	2 / 60 (3.33%)
occurrences (all)	15	25	2
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	24 / 57 (42.11%)	15 / 60 (25.00%)	19 / 60 (31.67%)
occurrences (all)	65	30	29

Fatigue			
subjects affected / exposed	19 / 57 (33.33%)	19 / 60 (31.67%)	21 / 60 (35.00%)
occurrences (all)	39	35	30
Malaise			
subjects affected / exposed	5 / 57 (8.77%)	1 / 60 (1.67%)	2 / 60 (3.33%)
occurrences (all)	5	1	2
Oedema peripheral			
subjects affected / exposed	8 / 57 (14.04%)	10 / 60 (16.67%)	12 / 60 (20.00%)
occurrences (all)	10	18	18
Peripheral swelling			
subjects affected / exposed	4 / 57 (7.02%)	3 / 60 (5.00%)	3 / 60 (5.00%)
occurrences (all)	5	4	4
Pyrexia			
subjects affected / exposed	5 / 57 (8.77%)	6 / 60 (10.00%)	10 / 60 (16.67%)
occurrences (all)	6	9	20
Influenza like illness			
subjects affected / exposed	3 / 57 (5.26%)	0 / 60 (0.00%)	0 / 60 (0.00%)
occurrences (all)	4	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 57 (10.53%)	9 / 60 (15.00%)	10 / 60 (16.67%)
occurrences (all)	10	12	12
Dysphonia			
subjects affected / exposed	1 / 57 (1.75%)	1 / 60 (1.67%)	3 / 60 (5.00%)
occurrences (all)	1	1	3
Dyspnoea			
subjects affected / exposed	12 / 57 (21.05%)	4 / 60 (6.67%)	15 / 60 (25.00%)
occurrences (all)	15	11	26
Dyspnoea exertional			
subjects affected / exposed	1 / 57 (1.75%)	3 / 60 (5.00%)	2 / 60 (3.33%)
occurrences (all)	3	4	4
Epistaxis			
subjects affected / exposed	0 / 57 (0.00%)	5 / 60 (8.33%)	7 / 60 (11.67%)
occurrences (all)	0	6	8
Nasal congestion			

subjects affected / exposed	2 / 57 (3.51%)	6 / 60 (10.00%)	2 / 60 (3.33%)
occurrences (all)	2	6	3
Oropharyngeal pain			
subjects affected / exposed	4 / 57 (7.02%)	0 / 60 (0.00%)	2 / 60 (3.33%)
occurrences (all)	4	0	2
Pleural effusion			
subjects affected / exposed	4 / 57 (7.02%)	1 / 60 (1.67%)	1 / 60 (1.67%)
occurrences (all)	7	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 57 (0.00%)	3 / 60 (5.00%)	0 / 60 (0.00%)
occurrences (all)	0	3	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	4 / 60 (6.67%)
occurrences (all)	1	0	4
Psychiatric disorders			
Insomnia			
subjects affected / exposed	6 / 57 (10.53%)	4 / 60 (6.67%)	4 / 60 (6.67%)
occurrences (all)	7	4	4
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 57 (7.02%)	1 / 60 (1.67%)	6 / 60 (10.00%)
occurrences (all)	5	1	13
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 57 (7.02%)	1 / 60 (1.67%)	6 / 60 (10.00%)
occurrences (all)	5	1	15
Blood alkaline phosphatase increased			
subjects affected / exposed	5 / 57 (8.77%)	3 / 60 (5.00%)	7 / 60 (11.67%)
occurrences (all)	8	5	14
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	3 / 60 (5.00%)
occurrences (all)	2	0	3
Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 57 (7.02%)	0 / 60 (0.00%)	6 / 60 (10.00%)
occurrences (all)	7	0	8
Neutrophil count decreased			

subjects affected / exposed occurrences (all)	3 / 57 (5.26%) 3	1 / 60 (1.67%) 2	4 / 60 (6.67%) 4
Weight decreased subjects affected / exposed occurrences (all)	6 / 57 (10.53%) 7	3 / 60 (5.00%) 3	3 / 60 (5.00%) 6
White blood cell count decreased subjects affected / exposed occurrences (all)	3 / 57 (5.26%) 5	1 / 60 (1.67%) 1	0 / 60 (0.00%) 0
Cardiac disorders			
Palpitations subjects affected / exposed occurrences (all)	4 / 57 (7.02%) 4	1 / 60 (1.67%) 1	0 / 60 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	1 / 57 (1.75%) 1	3 / 60 (5.00%) 4	1 / 60 (1.67%) 1
Tachycardia subjects affected / exposed occurrences (all)	5 / 57 (8.77%) 6	1 / 60 (1.67%) 1	1 / 60 (1.67%) 1
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	6 / 57 (10.53%) 8	6 / 60 (10.00%) 7	3 / 60 (5.00%) 4
Dysgeusia subjects affected / exposed occurrences (all)	7 / 57 (12.28%) 7	7 / 60 (11.67%) 7	5 / 60 (8.33%) 6
Headache subjects affected / exposed occurrences (all)	8 / 57 (14.04%) 10	7 / 60 (11.67%) 8	7 / 60 (11.67%) 7
Hypoaesthesia subjects affected / exposed occurrences (all)	1 / 57 (1.75%) 2	2 / 60 (3.33%) 4	3 / 60 (5.00%) 5
Neuropathy peripheral subjects affected / exposed occurrences (all)	4 / 57 (7.02%) 5	3 / 60 (5.00%) 5	4 / 60 (6.67%) 10
Paraesthesia			

subjects affected / exposed occurrences (all)	5 / 57 (8.77%) 10	5 / 60 (8.33%) 6	7 / 60 (11.67%) 13
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	26 / 57 (45.61%) 61	18 / 60 (30.00%) 29	14 / 60 (23.33%) 34
Peripheral motor neuropathy subjects affected / exposed occurrences (all)	1 / 57 (1.75%) 1	3 / 60 (5.00%) 3	0 / 60 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	39 / 57 (68.42%) 108	29 / 60 (48.33%) 107	34 / 60 (56.67%) 109
Leukopenia subjects affected / exposed occurrences (all)	7 / 57 (12.28%) 12	3 / 60 (5.00%) 8	6 / 60 (10.00%) 17
Neutropenia subjects affected / exposed occurrences (all)	20 / 57 (35.09%) 47	11 / 60 (18.33%) 22	20 / 60 (33.33%) 46
Thrombocytopenia subjects affected / exposed occurrences (all)	7 / 57 (12.28%) 10	2 / 60 (3.33%) 2	5 / 60 (8.33%) 6
Ear and labyrinth disorders			
Vertigo subjects affected / exposed occurrences (all)	3 / 57 (5.26%) 3	1 / 60 (1.67%) 1	1 / 60 (1.67%) 1
Eye disorders			
Dry eye subjects affected / exposed occurrences (all)	2 / 57 (3.51%) 2	3 / 60 (5.00%) 3	1 / 60 (1.67%) 1
Lacrimation increased subjects affected / exposed occurrences (all)	8 / 57 (14.04%) 8	6 / 60 (10.00%) 7	2 / 60 (3.33%) 3
Visual impairment subjects affected / exposed occurrences (all)	4 / 57 (7.02%) 5	0 / 60 (0.00%) 0	3 / 60 (5.00%) 3
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	3 / 57 (5.26%)	3 / 60 (5.00%)	2 / 60 (3.33%)
occurrences (all)	3	4	5
Abdominal distension			
subjects affected / exposed	9 / 57 (15.79%)	6 / 60 (10.00%)	4 / 60 (6.67%)
occurrences (all)	18	8	5
Abdominal pain			
subjects affected / exposed	21 / 57 (36.84%)	16 / 60 (26.67%)	20 / 60 (33.33%)
occurrences (all)	34	21	30
Abdominal pain lower			
subjects affected / exposed	0 / 57 (0.00%)	4 / 60 (6.67%)	3 / 60 (5.00%)
occurrences (all)	0	4	3
Abdominal pain upper			
subjects affected / exposed	7 / 57 (12.28%)	9 / 60 (15.00%)	6 / 60 (10.00%)
occurrences (all)	9	14	9
Ascites			
subjects affected / exposed	6 / 57 (10.53%)	5 / 60 (8.33%)	4 / 60 (6.67%)
occurrences (all)	9	7	7
Constipation			
subjects affected / exposed	25 / 57 (43.86%)	19 / 60 (31.67%)	17 / 60 (28.33%)
occurrences (all)	39	26	25
Diarrhoea			
subjects affected / exposed	22 / 57 (38.60%)	16 / 60 (26.67%)	15 / 60 (25.00%)
occurrences (all)	39	33	25
Dry mouth			
subjects affected / exposed	2 / 57 (3.51%)	3 / 60 (5.00%)	2 / 60 (3.33%)
occurrences (all)	2	3	5
Dyspepsia			
subjects affected / exposed	7 / 57 (12.28%)	4 / 60 (6.67%)	4 / 60 (6.67%)
occurrences (all)	7	4	5
Gastrooesophageal reflux disease			
subjects affected / exposed	4 / 57 (7.02%)	0 / 60 (0.00%)	2 / 60 (3.33%)
occurrences (all)	6	0	2
Intestinal obstruction			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	4 / 60 (6.67%)
occurrences (all)	1	0	5

Nausea			
subjects affected / exposed	41 / 57 (71.93%)	30 / 60 (50.00%)	27 / 60 (45.00%)
occurrences (all)	73	42	42
Stomatitis			
subjects affected / exposed	15 / 57 (26.32%)	3 / 60 (5.00%)	3 / 60 (5.00%)
occurrences (all)	18	4	3
Vomiting			
subjects affected / exposed	27 / 57 (47.37%)	18 / 60 (30.00%)	15 / 60 (25.00%)
occurrences (all)	49	31	22
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	3 / 57 (5.26%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences (all)	4	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	21 / 57 (36.84%)	22 / 60 (36.67%)	24 / 60 (40.00%)
occurrences (all)	24	29	29
Dry skin			
subjects affected / exposed	3 / 57 (5.26%)	3 / 60 (5.00%)	2 / 60 (3.33%)
occurrences (all)	8	3	2
Eczema			
subjects affected / exposed	3 / 57 (5.26%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences (all)	5	2	0
Erythema			
subjects affected / exposed	2 / 57 (3.51%)	4 / 60 (6.67%)	0 / 60 (0.00%)
occurrences (all)	5	6	0
Nail discolouration			
subjects affected / exposed	5 / 57 (8.77%)	5 / 60 (8.33%)	4 / 60 (6.67%)
occurrences (all)	9	6	4
Nail disorder			
subjects affected / exposed	9 / 57 (15.79%)	4 / 60 (6.67%)	1 / 60 (1.67%)
occurrences (all)	20	4	1
Nail dystrophy			
subjects affected / exposed	3 / 57 (5.26%)	0 / 60 (0.00%)	1 / 60 (1.67%)
occurrences (all)	6	0	2
Nail pigmentation			

subjects affected / exposed	2 / 57 (3.51%)	3 / 60 (5.00%)	0 / 60 (0.00%)
occurrences (all)	3	3	0
Nail ridging			
subjects affected / exposed	1 / 57 (1.75%)	4 / 60 (6.67%)	0 / 60 (0.00%)
occurrences (all)	1	4	0
Onychalgia			
subjects affected / exposed	4 / 57 (7.02%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences (all)	5	1	0
Onycholysis			
subjects affected / exposed	8 / 57 (14.04%)	6 / 60 (10.00%)	3 / 60 (5.00%)
occurrences (all)	14	6	4
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	5 / 57 (8.77%)	3 / 60 (5.00%)	1 / 60 (1.67%)
occurrences (all)	7	7	1
Pruritus			
subjects affected / exposed	4 / 57 (7.02%)	3 / 60 (5.00%)	7 / 60 (11.67%)
occurrences (all)	4	3	11
Rash			
subjects affected / exposed	11 / 57 (19.30%)	4 / 60 (6.67%)	2 / 60 (3.33%)
occurrences (all)	19	5	3
Skin hyperpigmentation			
subjects affected / exposed	4 / 57 (7.02%)	3 / 60 (5.00%)	1 / 60 (1.67%)
occurrences (all)	8	5	1
Skin toxicity			
subjects affected / exposed	5 / 57 (8.77%)	1 / 60 (1.67%)	2 / 60 (3.33%)
occurrences (all)	7	1	3
Dermatitis acneiform			
subjects affected / exposed	7 / 57 (12.28%)	2 / 60 (3.33%)	1 / 60 (1.67%)
occurrences (all)	9	4	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	2 / 57 (3.51%)	3 / 60 (5.00%)	4 / 60 (6.67%)
occurrences (all)	3	3	4
Pollakiuria			

subjects affected / exposed	1 / 57 (1.75%)	3 / 60 (5.00%)	4 / 60 (6.67%)
occurrences (all)	2	3	4
Urinary incontinence			
subjects affected / exposed	3 / 57 (5.26%)	1 / 60 (1.67%)	3 / 60 (5.00%)
occurrences (all)	4	1	3
Hydronephrosis			
subjects affected / exposed	3 / 57 (5.26%)	1 / 60 (1.67%)	0 / 60 (0.00%)
occurrences (all)	3	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	14 / 57 (24.56%)	9 / 60 (15.00%)	7 / 60 (11.67%)
occurrences (all)	17	19	9
Back pain			
subjects affected / exposed	10 / 57 (17.54%)	7 / 60 (11.67%)	9 / 60 (15.00%)
occurrences (all)	14	8	13
Bone pain			
subjects affected / exposed	6 / 57 (10.53%)	4 / 60 (6.67%)	6 / 60 (10.00%)
occurrences (all)	6	7	6
Muscle spasms			
subjects affected / exposed	1 / 57 (1.75%)	1 / 60 (1.67%)	8 / 60 (13.33%)
occurrences (all)	1	2	20
Muscular weakness			
subjects affected / exposed	3 / 57 (5.26%)	6 / 60 (10.00%)	3 / 60 (5.00%)
occurrences (all)	3	8	4
Myalgia			
subjects affected / exposed	12 / 57 (21.05%)	4 / 60 (6.67%)	10 / 60 (16.67%)
occurrences (all)	16	5	15
Neck pain			
subjects affected / exposed	3 / 57 (5.26%)	4 / 60 (6.67%)	2 / 60 (3.33%)
occurrences (all)	3	5	2
Pain in extremity			
subjects affected / exposed	8 / 57 (14.04%)	10 / 60 (16.67%)	8 / 60 (13.33%)
occurrences (all)	14	18	19
Infections and infestations			

Cystitis			
subjects affected / exposed	1 / 57 (1.75%)	1 / 60 (1.67%)	3 / 60 (5.00%)
occurrences (all)	1	1	3
Upper respiratory tract infection			
subjects affected / exposed	2 / 57 (3.51%)	1 / 60 (1.67%)	6 / 60 (10.00%)
occurrences (all)	2	1	8
Urinary tract infection			
subjects affected / exposed	8 / 57 (14.04%)	4 / 60 (6.67%)	3 / 60 (5.00%)
occurrences (all)	9	5	6
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	20 / 57 (35.09%)	13 / 60 (21.67%)	10 / 60 (16.67%)
occurrences (all)	32	15	16
Hypoalbuminaemia			
subjects affected / exposed	3 / 57 (5.26%)	3 / 60 (5.00%)	4 / 60 (6.67%)
occurrences (all)	5	5	7
Hypokalaemia			
subjects affected / exposed	14 / 57 (24.56%)	3 / 60 (5.00%)	5 / 60 (8.33%)
occurrences (all)	21	6	11
Hypomagnesaemia			
subjects affected / exposed	9 / 57 (15.79%)	5 / 60 (8.33%)	11 / 60 (18.33%)
occurrences (all)	18	9	28
Hyponatraemia			
subjects affected / exposed	3 / 57 (5.26%)	3 / 60 (5.00%)	2 / 60 (3.33%)
occurrences (all)	3	4	2
Hypophosphataemia			
subjects affected / exposed	4 / 57 (7.02%)	1 / 60 (1.67%)	2 / 60 (3.33%)
occurrences (all)	5	2	7

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 March 2019	1. Updated Inclusion Criterion 5 to state that CA-125 must be at least twice the upper limit of the reference range or ≥ 70 U/mL. 2. Inclusion Criterion 8 was added: "Appropriate to treat with nab-paclitaxel, in the opinion of the Investigator." 3. Updated the ORR term overall response rate to objective response rate. The objective response rate did not require a confirmed CR or PR. The BoR rate was removed since it would have been redundant with the objective response rate. 4. Specified that Screening laboratory samples can be used for the Cycle 1 Day 1 visit if taken within 48 hours of the first dose of study treatment. 5. Removed the lead-in visit; procedures that occurred on the first day of dosing were moved to Cycle 1, Day 1. 6. Clarified precautions for administering nab-paclitaxel concomitant medications known to inhibit or induce CYP2C8. 7. Added the option for Arm A and Crossover patients to dose escalate in 25-mg increments per 28-day cycle, after Cycle 1 and 2 only, up to a maximum relacorilant dose of 150 mg once daily. 8. Updated the day for the first dose of relacorilant to Cycle 1, Day 1 in Arms A and B. 9. Clarified pegfilgrastim can be used as prophylactic G-CSF after nab-paclitaxel infusion in patients with a chemotherapy-free window of 2 weeks. 10. Added an objective to assess CA-125 response (by GCIG criteria) and the combined response endpoint based on RECIST v1.1 and GCIG in the Crossover.
23 October 2019	1. Revised inclusion criteria to include platinum-refractory patients and allow up to 4 prior lines of therapy. 2. Patients discontinuing treatment or completing the study should continue to undergo tumor assessments every 8 weeks until unequivocal PD. Subsequent treatment information will be collected every 8 weeks in patients who are still undergoing radiographic tumor assessments. 3. Investigators must notify the Sponsor within 48 hours if a patient discontinues treatment. 4. After the 30-day follow-up period, any worsening AEs, SAEs related to study treatment, or deaths considered related to study treatment must be recorded. 5. Cranberry was no longer a prohibited food. 6. Added relacorilant 100-mg capsule. 7. Added additional guidance details for reducing and/or delaying nab-paclitaxel and/or relacorilant dose in case of toxicity.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported