Clinical trial results:
SORAYA: A Phase 3, Single Arm Study of Mirvetuximab Soravtansine in Platinum-Resistant, Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression

Summary

EudraCT number	2020-000179-19
Trial protocol	IE DE BG BE IT
Global end of trial date	16 November 2022

Results information

Result version number	v1 (current)
This version publication date	25 November 2023
First version publication date	25 November 2023

Trial information

Trial identification

Sponsor protocol code	IMGN853-0417

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04296890
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ImmunoGen, Inc.
Sponsor organisation address	830 Winter Street, Waltham, United States, MA 02451
Public contact	CMO, ImmunoGen, ImmunoGen, Inc., +1 781-895-0600, clinicaltrials@immunogen.com
Scientific contact	CMO, ImmunoGen, ImmunoGen, Inc., +1 781-895-0600, clinicaltrials@immunogen.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	29 April 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial was to determine the efficacy of mirvetuximab soravtansine in participants with platinum-resistant ovarian cancer (PROC) and high folate receptor alpha (FRα) expression.

Protection of trial subjects:

This clinical study was conducted by the sponsor, the investigator, delegated investigator staff and sub-investigator(s), in accordance with the protocol, ethical principles that have their origins in the Declaration of Helsinki, the International Council on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical Practice (GCP), and all applicable local regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 July 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Israel: 2
Country: Number of subjects enrolled	United States: 24
Country: Number of subjects enrolled	Australia: 11
Country: Number of subjects enrolled	Spain: 26
Country: Number of subjects enrolled	Belgium: 11
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Ireland: 6
Country: Number of subjects enrolled	Italy: 23
Worldwide total number of subjects	106
EEA total number of subjects	69

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)	59
From 65 to 84 years	46
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants were enrolled at 39 sites in North America, Europe, and Asia Pacific.

Period 1

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

Arms

Arm title	Mirvetuximab Soravtansine

Arm description:

Participants received single-agent mirvetuximab soravtansine (MIRV) at 6 milligrams (mg)/kilogram (kg) adjusted ideal body weight (AIBW) administered intravenously (IV) on Day 1 of every 3-week cycle (Q3W).

Arm type	Experimental
Investigational medicinal product name	Mirvetuximab Soravtansine
Investigational medicinal product code	IMGN853
Other name	MIRV
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Mirvetuximab soravtansine was administered per dose and schedule specified in the arm description.

Number of subjects in period 1	Mirvetuximab Soravtansine
Started	106
INV Efficacy Evaluable Population	105
Completed	0
Not completed	106
Consent withdrawn by subject	1
Study terminated by Sponsor	38
Death	62
Other than specified	2
Lost to follow-up	3

Baseline characteristics

Reporting groups	
Reporting group title	Mirvetuximab Soravtansine
Reporting group description:	
Participants received single-agent mirvetuximab soravtansine (MIRV) at 6 milligrams (mg)/kilogram (kg) adjusted ideal body weight (AIBW) administered intravenously (IV) on Day 1 of every 3-week cycle (Q3W).	

Reporting group values	Mirvetuximab Soravtansine	Total	
Number of subjects	106	106	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 62 ± 10	 -	
Gender categorical Units: Subjects			
Female	106	106	
Male	0	0	
Race Units: Subjects			
White	102	102	
Asian	2	2	
Not Reported	2	2	
Ethnicity Units: Subjects			
Hispanic or Latino	2	2	
Not Hispanic or Latino	99	99	
Unknown or Not Reported	5	5	

End points

End points reporting groups

Reporting group title	Mirvetuximab Soravtansine

Reporting group description:

Participants received single-agent mirvetuximab soravtansine (MIRV) at 6 milligrams (mg)/kilogram (kg) adjusted ideal body weight (AIBW) administered intravenously (IV) on Day 1 of every 3-week cycle (Q3W).

Primary: Objective Response Rate (ORR): Percentage of Participants With Objective Response as Assessed by the Investigator Using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)

End point title	Objective Response Rate (ORR): Percentage of Participants With Objective Response as Assessed by the Investigator Using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)[1]

End point description:

ORR was defined as percentage of participants with a confirmed best overall response (BOR) of complete response (CR) or partial response (PR). CR: Disappearance of all target or non-target lesions. All pathological or non-pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 millimeters (mm). PR: At least 30% decrease in the sum of the longest diameters (SoD) of target lesions, taking as reference the baseline SoD. The investigator (INV) Efficacy Evaluable population was defined as all participants who received at least 1 dose of study drug and who had measurable disease at baseline by investigator assessment per RECIST 1.1.

End point type	Primary

End point timeframe:

Up to 30 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not planned for this endpoint.

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	105			
Units: percentage of participants				
number (confidence interval 95%)	32.4 (23.6 to 42.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) as Assessed by the Investigator Using RECIST v1.1

End point title	Duration of Response (DOR) as Assessed by the Investigator Using RECIST v1.1

End point description:

DOR was defined as the time from the date of the first response (CR or PR), until the date of progressive disease (PD) or death from any cause, whichever occurred first. DOR for participants who had not

progressed or died at the time of analysis was censored at the date of their last tumor assessment. PD: At least a 20% increase in the SoD of target lesion, taken as reference the smallest (nadir) SoD since and including baseline. In addition to the relative increase of 20%, the SoD must also demonstrate an absolute increase of at least 5 mm. Unequivocal progression of non-target lesions. Unequivocal progression should not normally trump target lesion status. It must be representative of overall disease status change, not a single lesion increase. DOR was estimated using the Kaplan-Meier method. All participants that showed a CR or PR according to RECIST 1.1 were analyzed.

End point type	Secondary

End point timeframe:

Up to 30 months

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	34			
Units: months				
median (confidence interval 95%)	6.93 (5.55 to 9.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With CA-125 Confirmed Clinical Response per Gynecologic Cancer Intergroup (GCIG) Criteria

End point title	Percentage of Participants With CA-125 Confirmed Clinical Response per Gynecologic Cancer Intergroup (GCIG) Criteria

End point description:

The GCIG CA-125 response was defined as at least 50% reduction in CA-125 levels from baseline. The response must have been confirmed and maintained for at least 28 days. The CA-125-Evaluable population was defined as all participants who received at least 1 dose of study drug and whose pretreatment sample was ≥2.0 times the upper limit of normal (ULN), within 2 weeks prior to first dose of mirvetuximab soravtansine, and who had at least 1 postbaseline CA-125 evaluation.

End point type	Secondary

End point timeframe:

Up to 30 months

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	86			
Units: percentage of participants				
number (confidence interval 95%)	46.5 (35.7 to 57.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) as Assessed by the Investigator Using RECIST v1.1

End point title	Progression-Free Survival (PFS) as Assessed by the Investigator Using RECIST v1.1

End point description:

PFS was defined as the time from initiation of study drug until the date of PD or death whichever occurred first, estimated using the Kaplan-Meier method. PD: At least a 20% increase in the SoD of target lesion, taken as reference the smallest (nadir) SoD since and including baseline. In addition to the relative increase of 20%, the SoD must also demonstrate an absolute increase of at least 5 mm. Unequivocal progression of non-target lesions and appearance of new lesions. Unequivocal progression should not normally trump target lesion status. It must be representative of overall disease status change, not a single lesion increase. INV Efficacy Evaluable population was defined as all participants who received at least 1 dose of study drug and who had measurable disease at baseline by investigator assessment per RECIST 1.1.

End point type	Secondary

End point timeframe:

Up to 30 months

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	105			
Units: months				
median (confidence interval 95%)	4.27 (3.71 to 5.22)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival Assessed by the Investigator Using RECIST v1.1

End point title	Overall Survival Assessed by the Investigator Using RECIST v1.1

End point description:

Overall survival was defined as the time from the date of first dose until the date of death from any cause, estimated using the Kaplan-Meier method. INV Efficacy Evaluable population was defined as all participants who received at least 1 dose of study drug and who had measurable disease at baseline by investigator assessment per RECIST 1.1.

End point type	Secondary

End point timeframe:

Up to 30 months

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	105			
Units: months				
median (confidence interval 95%)	15.0 (11.5 to 18.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Participants With Treatment-emergent Adverse Events (TEAEs)

End point description:

An adverse event (AE) was defined as any untoward medical occurrence that develops or worsens in severity during the conduct of a clinical study and does not necessarily have a causal relationship to study drug. TEAEs were defined as AEs with an onset date on or after the first dose of Study drug, and within 30 days of the last dose of study drug or prior to the start of a new anticancer treatment, whichever occurred first. A summary of all Serious Adverse Events (SAEs) and Other Adverse Events (nonserious) regardless of causality is located in the 'Reported Adverse Events' Section. The Safety population was defined as participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Up to 30 months

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	106			
Units: participants	105			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 30 months

Adverse event reporting additional description:

Deaths (all-cause) were assessed from first dose until death (survival follow-up). Serious and nonserious AEs (Safety population) were assessed from first dose and within 30 days of the last dose or prior to the start of a new anticancer treatment, whichever occurred first.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Mirvetuximab Soravtansine

Reporting group description:

Participants received single-agent mirvetuximab soravtansine (MIRV) at 6 milligrams (mg)/kilogram (kg) adjusted ideal body weight (AIBW) administered intravenously (IV) on Day 1 of every 3-week cycle (Q3W).

Serious adverse events	Mirvetuximab Soravtansine		
Total subjects affected by serious adverse events			
subjects affected / exposed	36 / 106 (33.96%)		
number of deaths (all causes)	62		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Vasculitis			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Administration site extravasation			

subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Disease progression			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Malaise			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	2 / 106 (1.89%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pneumonitis			
subjects affected / exposed	2 / 106 (1.89%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	1 / 1		
Psychiatric disorders			

Substance-induced psychotic disorder				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Ankle fracture				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infusion related reaction				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Atrial fibrillation				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Brain stem syndrome				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral sensory neuropathy				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				

subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	5 / 106 (4.72%)			
occurrences causally related to treatment / all	1 / 8			
deaths causally related to treatment / all	0 / 1			
Colitis microscopic				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal haemorrhage				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	2 / 106 (1.89%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intestinal perforation				
subjects affected / exposed	1 / 106 (0.94%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestinal obstruction				

subjects affected / exposed	2 / 106 (1.89%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophagitis			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			
subjects affected / exposed	5 / 106 (4.72%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholestasis			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			

Clostridium difficile infection			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis bacterial			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Severe protein calorie malnutrition			
subjects affected / exposed	1 / 106 (0.94%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Mirvetuximab Soravtansine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	102 / 106 (96.23%)		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	12 / 106 (11.32%)		
occurrences (all)	14		
Aspartate aminotransferase increased			
subjects affected / exposed	16 / 106 (15.09%)		
occurrences (all)	18		
Blood alkaline phosphatase increased			
subjects affected / exposed	12 / 106 (11.32%)		
occurrences (all)	15		
Gamma-glutamyltransferase increased			

subjects affected / exposed occurrences (all) Weight decreased subjects affected / exposed occurrences (all)	13 / 106 (12.26%) 18 6 / 106 (5.66%) 6		
Nervous system disorders Dysgeusia subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Neuropathy peripheral subjects affected / exposed occurrences (all)	 8 / 106 (7.55%) 10 10 / 106 (9.43%) 15 19 / 106 (17.92%) 22		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all) Neutropenia subjects affected / exposed occurrences (all) Thrombocytopenia subjects affected / exposed occurrences (all)	 14 / 106 (13.21%) 33 16 / 106 (15.09%) 31 10 / 106 (9.43%) 14		
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Oedema peripheral subjects affected / exposed occurrences (all)	 22 / 106 (20.75%) 31 32 / 106 (30.19%) 49 6 / 106 (5.66%) 6		
Eye disorders			

Cataract			
subjects affected / exposed	21 / 106 (19.81%)		
occurrences (all)	39		
Dry eye			
subjects affected / exposed	30 / 106 (28.30%)		
occurrences (all)	37		
Eye pain			
subjects affected / exposed	9 / 106 (8.49%)		
occurrences (all)	9		
Keratopathy			
subjects affected / exposed	34 / 106 (32.08%)		
occurrences (all)	72		
Photophobia			
subjects affected / exposed	17 / 106 (16.04%)		
occurrences (all)	21		
Punctate keratitis			
subjects affected / exposed	9 / 106 (8.49%)		
occurrences (all)	11		
Vision blurred			
subjects affected / exposed	49 / 106 (46.23%)		
occurrences (all)	100		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	13 / 106 (12.26%)		
occurrences (all)	16		
Abdominal pain			
subjects affected / exposed	26 / 106 (24.53%)		
occurrences (all)	36		
Abdominal pain upper			
subjects affected / exposed	13 / 106 (12.26%)		
occurrences (all)	18		
Ascites			
subjects affected / exposed	6 / 106 (5.66%)		
occurrences (all)	13		
Constipation			

subjects affected / exposed occurrences (all)	32 / 106 (30.19%) 47		
Diarrhoea subjects affected / exposed occurrences (all)	33 / 106 (31.13%) 52		
Dyspepsia subjects affected / exposed occurrences (all)	6 / 106 (5.66%) 15		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	8 / 106 (7.55%) 9		
Nausea subjects affected / exposed occurrences (all)	41 / 106 (38.68%) 77		
Vomiting subjects affected / exposed occurrences (all)	20 / 106 (18.87%) 35		
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	7 / 106 (6.60%) 8		
Dyspnoea subjects affected / exposed occurrences (all)	11 / 106 (10.38%) 14		
Pneumonitis subjects affected / exposed occurrences (all)	9 / 106 (8.49%) 10		
Skin and subcutaneous tissue disorders			
Erythema subjects affected / exposed occurrences (all)	6 / 106 (5.66%) 7		
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	17 / 106 (16.04%) 20		
Back pain			

subjects affected / exposed	8 / 106 (7.55%)		
occurrences (all)	9		
Myalgia			
subjects affected / exposed	11 / 106 (10.38%)		
occurrences (all)	13		
Pain in extremity			
subjects affected / exposed	6 / 106 (5.66%)		
occurrences (all)	9		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	10 / 106 (9.43%)		
occurrences (all)	14		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	20 / 106 (18.87%)		
occurrences (all)	29		
Hypokalaemia			
subjects affected / exposed	11 / 106 (10.38%)		
occurrences (all)	16		
Hypomagnesaemia			
subjects affected / exposed	11 / 106 (10.38%)		
occurrences (all)	13		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 December 2019	The main elements of the protocol amendment include the following: • Increase in the total number of enrolled/evaluable participants. • Addition of exploratory objective to evaluate potential tumor-based biomarkers predictive of response to mirvetuximab soravtansine. • Noted allowance for a participant's legally authorized representative to sign the informed consent form in the inclusion criteria, consistent with existing language in the rest of the protocol. • Added recommendation that participants who have discontinued study drug for reasons other than progressive disease prior to Week 36 (from Cycle 1 Day 1), and who have not received another anticancer therapy, be scanned every 6 weeks up to Week 36. This update is consistent with the frequency of disease assessments for all participants on treatment. • Revised the definition of efficacy evaluable population.
28 August 2020	The primary reasons for amending this protocol were to update the inclusion and exclusion criteria, add the risk benefit conclusion, and include language to accommodate the COVID pandemic. The following key changes were made: • Updates to participant inclusion and exclusion criteria • Clarification of prescreening informed consent form (ICF) • Addition of risk benefit conclusion of mirvetuximab soravtansine • Post-treatment pregnancy test language added • Mirvetuximab soravtansine discontinuation criteria further defined • CYP3A4/MRD1 interaction language updated • Contraception details clarified • Radiographical imaging assessment timing and details updated • Recording of AEs/SAEs and retention of data updated • Study monitoring and training language updated to accommodate the existing COVID pandemic.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported