Clinical trial results:
PICCOLO: A Phase 2, Single Arm Study of Mirvetuximab Soravtansine in Recurrent Platinum-Sensitive, High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression

Summary

EudraCT number	2021-003592-34
Trial protocol	ES BE FR IT DE
Global end of trial date	12 December 2024

Results information

Result version number	v1 (current)
This version publication date	18 December 2025
First version publication date	18 December 2025

Trial information

Trial identification

Sponsor protocol code	IMGN853-0419

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05041257
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6 4UB
Public contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com
Scientific contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.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 December 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

PICCOLO (IMGN853-0419) was a Phase 2 multicenter, open label study designed to evaluate the safety and efficacy of Mirvetuximab Soravtansine in participants with platinum-sensitive ovarian, primary peritoneal or fallopian tube cancers with high folate receptor-alpha (FRα) expression.

Protection of trial subjects:

The study was conducted in accordance with the protocol International Conference on Harmonisation (ICH) guidelines, applicable regulations, and guidelines governing clinical study conduct and ethical principles that have their origin in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 October 2021
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	Australia: 3
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	France: 5
Country: Number of subjects enrolled	Ireland: 4
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	Spain: 23
Country: Number of subjects enrolled	United States: 26
Worldwide total number of subjects	79
EEA total number of subjects	50

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)	33
From 65 to 84 years	46
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 79 participants were enrolled in the trial and received at least 1 dose of study drug.

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 at 6 mg/kg adjusted by ideal body weight administered through IV infusion on Day 1 of every 3-week cycle.

Arm type	Experimental
Investigational medicinal product name	Mirvetuximab Soravtansine
Investigational medicinal product code	
Other name	MIRV, IMGN853
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	79
Received at least 1 dose of study drug	79
Completed	0
Not completed	79
In follow-up at time of study completion	39
Death	37
Lost to follow-up	3

Baseline characteristics

Reporting groups	
Reporting group title	Mirvetuximab Soravtansine
Reporting group description:	
Participants received single-agent mirvetuximab soravtansine at 6 mg/kg adjusted by ideal body weight administered through IV infusion on Day 1 of every 3-week cycle.	

Reporting group values	Mirvetuximab Soravtansine	Total	
Number of subjects	79	79	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	33	33	
From 65-84 years	46	46	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	64.1		
standard deviation	± 10.16	-	
Gender categorical Units: Subjects			
Female	79	79	
Male	0	0	
Ethnicity Units: Subjects			
Hispanic or Latino	2	2	
Not Hispanic or Latino	68	68	
Unknown or Not Reported	9	9	
Race Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	1	1	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	4	4	
White	65	65	
More than one race	0	0	
Unknown or Not Reported	9	9	

End points

End points reporting groups

Reporting group title	Mirvetuximab Soravtansine

Reporting group description:

Participants received single-agent mirvetuximab soravtansine at 6 mg/kg adjusted by ideal body weight administered through IV infusion on Day 1 of every 3-week cycle.

Primary: Objective Response Rate (ORR) Assessed by Investigator Per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1])

End point title	Objective Response Rate (ORR) Assessed by Investigator Per 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.

Efficacy Evaluable Population Per Investigator included all participants who received at least 1 dose of mirvetuximab soravtansine and had measurable disease at baseline per Investigator.

End point type	Primary

End point timeframe:

Up to 3 years

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: Only summary statistics were planned for this endpoint.

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: percentage of participants				
number (confidence interval 95%)	51.9 (40.4 to 63.3)			

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 developed or worsened in severity during the conduct of a clinical study and does not necessarily had 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.

Safety Population included all participants who received at least 1 dose of mirvetuximab soravtansine.

End point type	Secondary

End point timeframe:

Up to 3 years

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: participants	78			

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.

CA-125 Response-Evaluable Population included all participants who received at least 1 dose of mirvetuximab soravtansine, 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 post-baseline CA-125 evaluation.

End point type	Secondary

End point timeframe:

Up to 3 years

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: percentage of participants				
number (confidence interval 95%)	74.5 (59.7 to 86.1)			

Statistical analyses

No statistical analyses for this end point

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

End point title	Duration of Response (DOR) 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. Efficacy Evaluable Population Per Investigator included all participants who received at least 1 dose of mirvetuximab soravtansine and had measurable disease at baseline per Investigator.

End point type	Secondary

End point timeframe:

Up to 3 years

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	41[2]			
Units: months				
median (confidence interval 95%)	8.25 (5.55 to 10.78)			

Notes:

[2] - "Subjects analysed" = participants with objective response.

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. "99999" = Due to insufficient number of participants with an event, upper limit of 95% confidence interval (CI) could not be calculated.

Efficacy Evaluable Population Per Investigator included all participants who received at least 1 dose of mirvetuximab soravtansine and had measurable disease at baseline per Investigator.

End point type	Secondary

End point timeframe:

Up to 3 years

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: months				
median (confidence interval 95%)	27.17 (23.79 to 99999)			

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.

Efficacy Evaluable Population Per Investigator included all participants who received at least 1 dose of mirvetuximab soravtansine and had measurable disease at baseline per Investigator.

End point type	Secondary

End point timeframe:

Up to 3 years

End point values	Mirvetuximab Soravtansine			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: months				
median (confidence interval 95%)	6.93 (5.85 to 9.59)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality and adverse event tables include events reported from the start of safety data collection to the end of the study. The median time on follow-up was 26.5 months.

Adverse event reporting additional description:

Safety Population included all participants who received at least 1 dose of mirvetuximab soravtansine.

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 at 6 mg/kg AIBW administered through IV infusion on Day 1 of every 3-week cycle.

Serious adverse events	Mirvetuximab Soravtansine		
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 79 (21.52%)		
number of deaths (all causes)	37		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
GASTROINTESTINAL STOMA COMPLICATION			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
ATAXIA			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

NEUROPATHY PERIPHERAL				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
THROMBOTIC STROKE				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
SYNCOPE				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
EXTRAVASATION				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
SUPRAPUBIC PAIN				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
KERATITIS				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
SUBILEUS				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
SMALL INTESTINAL OBSTRUCTION				

subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
NAUSEA				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
INTESTINAL OBSTRUCTION				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
VOMITING				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
PNEUMOTHORAX				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
PNEUMONITIS				
subjects affected / exposed	4 / 79 (5.06%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 2			
Infections and infestations				
PYELONEPHRITIS				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
SEPTIC SHOCK				
subjects affected / exposed	1 / 79 (1.27%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			

LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
CYSTITIS			
subjects affected / exposed	1 / 79 (1.27%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
PNEUMONIA			
subjects affected / exposed	1 / 79 (1.27%)		
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	77 / 79 (97.47%)		
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	6		
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	24 / 79 (30.38%)		
occurrences (all)	40		
FATIGUE			
subjects affected / exposed	14 / 79 (17.72%)		
occurrences (all)	22		
PYREXIA			
subjects affected / exposed	8 / 79 (10.13%)		
occurrences (all)	8		
Respiratory, thoracic and mediastinal disorders			

DYSPNOEA			
subjects affected / exposed	8 / 79 (10.13%)		
occurrences (all)	11		
COUGH			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	7		
PNEUMONITIS			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	6		
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	4		
INSOMNIA			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	6		
Investigations			
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	17 / 79 (21.52%)		
occurrences (all)	25		
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	15 / 79 (18.99%)		
occurrences (all)	23		
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	5		
WEIGHT DECREASED			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	7		
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	7 / 79 (8.86%)		
occurrences (all)	8		
Nervous system disorders			

PARAESTHESIA			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	10		
PERIPHERAL SENSORY NEUROPATHY			
subjects affected / exposed	7 / 79 (8.86%)		
occurrences (all)	11		
NEUROTOXICITY			
subjects affected / exposed	10 / 79 (12.66%)		
occurrences (all)	14		
DIZZINESS			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	5		
DYSGEUSIA			
subjects affected / exposed	9 / 79 (11.39%)		
occurrences (all)	10		
HEADACHE			
subjects affected / exposed	13 / 79 (16.46%)		
occurrences (all)	18		
NEUROPATHY PERIPHERAL			
subjects affected / exposed	22 / 79 (27.85%)		
occurrences (all)	37		
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	7 / 79 (8.86%)		
occurrences (all)	11		
NEUTROPENIA			
subjects affected / exposed	11 / 79 (13.92%)		
occurrences (all)	34		
THROMBOCYTOPENIA			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	9		
Eye disorders			
DRY EYE			
subjects affected / exposed	32 / 79 (40.51%)		
occurrences (all)	49		
CORNEAL EPITHELIAL MICROCYSTS			

subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	11		
KERATITIS			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	12		
EYE PAIN			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	9		
VITREOUS FLOATERS			
subjects affected / exposed	6 / 79 (7.59%)		
occurrences (all)	6		
VISUAL ACUITY REDUCED			
subjects affected / exposed	7 / 79 (8.86%)		
occurrences (all)	9		
VISION BLURRED			
subjects affected / exposed	52 / 79 (65.82%)		
occurrences (all)	116		
PHOTOPHOBIA			
subjects affected / exposed	13 / 79 (16.46%)		
occurrences (all)	19		
KERATOPATHY			
subjects affected / exposed	26 / 79 (32.91%)		
occurrences (all)	57		
CATARACT			
subjects affected / exposed	27 / 79 (34.18%)		
occurrences (all)	41		
Gastrointestinal disorders			
NAUSEA			
subjects affected / exposed	29 / 79 (36.71%)		
occurrences (all)	42		
STOMATITIS			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	5		
FLATULENCE			
subjects affected / exposed	4 / 79 (5.06%)		
occurrences (all)	5		

VOMITING subjects affected / exposed occurrences (all)	14 / 79 (17.72%) 18		
DIARRHOEA subjects affected / exposed occurrences (all)	24 / 79 (30.38%) 46		
CONSTIPATION subjects affected / exposed occurrences (all)	14 / 79 (17.72%) 17		
ABDOMINAL PAIN subjects affected / exposed occurrences (all)	14 / 79 (17.72%) 18		
ABDOMINAL DISTENSION subjects affected / exposed occurrences (all)	6 / 79 (7.59%) 6		
Skin and subcutaneous tissue disorders ERYTHEMA subjects affected / exposed occurrences (all)	4 / 79 (5.06%) 4		
Musculoskeletal and connective tissue disorders ARTHRALGIA subjects affected / exposed occurrences (all)	19 / 79 (24.05%) 24		
BACK PAIN subjects affected / exposed occurrences (all)	4 / 79 (5.06%) 4		
MYALGIA subjects affected / exposed occurrences (all)	7 / 79 (8.86%) 9		
PAIN IN EXTREMITY subjects affected / exposed occurrences (all)	6 / 79 (7.59%) 7		
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	13 / 79 (16.46%) 13		

Metabolism and nutrition disorders			
HYPOKALAEMIA			
subjects affected / exposed	8 / 79 (10.13%)		
occurrences (all)	12		
HYPOMAGNESAEMIA			
subjects affected / exposed	9 / 79 (11.39%)		
occurrences (all)	12		
HYPONATRAEMIA			
subjects affected / exposed	5 / 79 (6.33%)		
occurrences (all)	9		
DECREASED APPETITE			
subjects affected / exposed	7 / 79 (8.86%)		
occurrences (all)	8		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 August 2021	The primary reasons for this protocol amendment were to clarify the translational and exploratory components of the protocol, incorporate the newly determined name of the protocol, and update the ocular exam requirements for assessment

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported