Record 1 of 1

Completed

First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Mirvetuximab Soravtansine in Adults With Ovarian Cancer and Other Folate Receptor 1 (FOLR1)-Positive Solid Tumors (IMGN853-0401)

ClinicalTrials.gov ID NCT01609556

Sponsor ImmunoGen, Inc.

Information provided by ImmunoGen, Inc. (Responsible Party)

Last Update Posted 2021-02-17

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to test mirvetuximab soravtansine (IMGN853) in participants with ovarian cancer and other FOLR-1 positive tumors.

Detailed Description

The study consists of a dose-escalation phase that will evaluate 2 dosing schedules (Schedule A and Schedule B) of mirvetuximab soravtansine and up to 5 dose-expansion groups at the maximum tolerated dose (MTD). The first 4 escalation cohorts will be single participant cohorts. Subsequent escalation cohorts will use a standard 3+3 design, with each cohort consisting of 3 or 4 to 6 participants. Data were collected and analysed for the escalation and expansion groups by dose schedule and not by individual dose.

Official Title

A Phase 1, First-in-Human Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of IMGN853 in Adults With Ovarian Cancer and Other FOLR1-Positive Solid Tumors

Conditions

Tumors

Intervention / Treatment

- Drug: Mirvetuximab soravtansine

Other Study ID Numbers

Study Start (Actual)

2012-06-28

Primary Completion (Actual)

2018-03-19

Study Completion (Actual)

2018-03-19

Enrollment (Actual)

206

Study Type

Interventional

Phase

Phase 1

Resource links provided by the National Library of Medicine

MedlinePlus Genetics (https://medlineplus.gov/genetics/) related topics: Ovarian cancer (https://medlineplus.gov/genetics/condition/ovarian-cancer)

MedlinePlus (https://medlineplus.gov/) related topics: Ovarian Cancer (https://medlineplus.gov/ovariancancer.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources: Ovarian Cancer (https://rarediseases.info.nih.gov/diseases/7295/ovarian-cancer) Ovarian Epithelial Cancer (https://rarediseases.info.nih.gov/diseases/9362/ovarian-epithelial-cancer)

FDA Drug and Device Resources (https://clinicaltrials.gov/fda-links)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the Contacts and Locations section in How to Read a Study Record (https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations).

This study has 12 locations

United States

Kansas Locations

Fairway, Kansas, United States, 66205
University of Kansas Medical Center Research Institute

Massachusetts Locations

Boston, Massachusetts, United States, 02062
Massachusetts General Hospital

Boston, Massachusetts, United States, 02115
Dana Farber Cancer Institute

Michigan Locations

Detroit, Michigan, United States, 48201
Barbara Ann Karmanos Cancer Institute

New York Locations

New York, New York, United States, 10065
Memorial Sloan Kettering Cancer Center

Ohio Locations

Columbus, Ohio, United States, 43210
Ohio State University

Oklahoma Locations

Oklahoma City, Oklahoma, United States, 73104
University of Oklahoma Stephenson Cancer Center

Pennsylvania Locations

Philadelphia, Pennsylvania, United States, 19111
Fox Chase Cancer Center

Tennessee Locations

Nashville, Tennessee, United States, 37203
Sarah Cannon Research Institute

Texas Locations

San Antonio, Texas, United States, 78229

CTRC at the University of Texas Health Science Center

Canada

Ontario Locations

Toronto, Ontario, Canada, M5G 2M9
Princess Margaret Hospital

Quebec Locations

Montreal, Quebec, Canada, H4A3J1
McGill University Health Centre

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria

- Participants with advanced solid tumor that is refractory to standard treatment, for which no standard treatment is available, or the participant refuses standard therapy.
- Participants must be willing to provide an archival tumor tissue block or slides for biomarker analysis.
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0 or 1.
- Time from prior therapy:
    1. Systemic anti-neoplastic therapy: five half-lives or four weeks, whichever is shorter (6 weeks for prior nitrosoureas or mitomycin C).
    2. Radiotherapy: wide-field radiotherapy (for example, greater than [>] 30 percent [%] of marrow-bearing bones) completed at least four weeks, or focal radiation completed at least two weeks, prior to starting study drug.
- Participants must have recovered or stabilized from all therapy-related toxicities.
- Major surgery (not including placement of vascular access device or tumor biopsies) must be completed four weeks prior to Day 1. Participants must have recovered or stabilized from the side effects prior to study treatment.
- Participants must have adequate hematologic, liver and kidney function.
- Participants with central nervous system (CNS) disease involvement are eligible if they have had brain metastases resected or have received radiation therapy ending at least 4 weeks prior to study day 1 and they meet all of the following criteria: Residual neurological symptoms less than or equal to (<=) Grade 1; No dexamethasone requirement; and Follow-up magnetic resonance imaging (MRI) shows no progression of treated lesions and no new lesions appearing.
- Participants must be willing and able to sign the informed consent form, and to adhere to the study visit schedule and other protocol requirements.
- Women of childbearing potential and men must agree to use effective contraceptive methods while on study and for at least twelve weeks after the last dose of study drug.
- Women of childbearing potential must have a negative pregnancy test prior to the first dose of study treatment.

Exclusion Criteria

- Grade >1 neuropathy.
- Any active or chronic corneal disorder, including, but not limited to the following: Sjogren's syndrome, Fuch's corneal dystrophy (requiring treatment), history of corneal transplantation, active herpetic keratitis, and also active ocular conditions requiring ongoing treatment/monitoring such as wet age-related macular degeneration requiring intravitreal injections, active diabetic retinopathy with macular edema, presence of papilledema, acquired monocular vision.
- Serious concurrent illness, including, but not limited to the following:
    1. Clinically relevant active infection including known active hepatitis B or C, Human Immunodeficiency Virus (HIV) infection, varicella-zoster virus (shingles) or cytomegalovirus infection or any other known concurrent infectious disease, requiring IV antibiotics within 2 weeks of study enrollment.
    2. Significant cardiac disease such as recent myocardial infarction (<=6 months prior to Day 1), unstable angina pectoris, uncontrolled congestive heart failure (New York Heart Association >class II), uncontrolled hypertension (greater than or equal to [>=] Common Terminology Criteria for Adverse Events Version 4.03 [CTCAE v4.03] Grade 3), uncontrolled cardiac arrhythmias, severe aortic stenosis, or >=Grade 3 cardiac toxicity following prior chemotherapy.
    3. History of multiple sclerosis or other demyelinating disease, Eaton-Lambert syndrome (para-neoplastic syndrome), history of hemorrhagic or ischemic stroke within the last six months, or alcoholic liver disease.
    4. Previous clinical diagnosis of treatment-related pneumonitis.
- Any other concomitant anti-cancer treatment such as immunotherapy, biotherapy, radiotherapy, chemotherapy, investigative therapy, or high-dose steroids; however, low dose steroids and Luteinizing Hormone Releasing Hormone (LHRH) at doses that have been stable for >=14 days are permitted for participants with prostate cancer.
- Known hypersensitivity to previous monoclonal antibody therapy or maytansinoids.
- Prior history of solid tumor malignancy within the last 3 years except for adequately treated basal cell or squamous cell skin cancer, in situ cervical cancer, in situ breast cancer, in situ prostate cancer (participants must have shown no evidence of active disease for 2 years prior to enrollment).
- Concomitant administration of folate-containing vitamins.
- Participants who have received prior allogeneic or autologous bone marrow transplants.
- Women of childbearing potential who are pregnant or breast feeding.

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Treatment
Allocation : Non-Randomized
Interventional Model : Parallel Assignment
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Experimental: Dose Escalation: Schedule A (Mirvetuximab Soravtansine Q3W) Participants will receive mirvetuximab soravtansine intravenous (IV) infusion on Day 1 of every 21-day (every 3 weeks [Q3W]) cycle. Dose escalation for this group schedule will start at 0.15 milligrams per kilogram (mg/kg) and proceed through 7.0 mg/kg. Doses calculated initially based on participant's total body weight (TBW); then from protocol amendment 5 onwards, calculated based on adjusted ideal body weight (AIBW). Participants will continue to receive mirvetuximab soravtansine (for clinical benefit) until unacceptable toxicity or withdrawal of consent, whichever comes first, or until the sponsor terminate the study.	Drug: Mirvetuximab soravtansine • Mirvetuximab soravtansine IV infusion will be administered as per dose and schedule specified in the respective arms. • Other Names: ◦ IMGN853
Experimental: Dose Escalation: Schedule B (Mirvetuximab Soravtansine Weekly) Participants will receive mirvetuximab soravtansine IV infusion on Days 1, 8, and 15 of every 28-day cycle. Dose escalation for this group schedule will start at 1.1 mg/kg (calculated based on AIBW) and proceed through 2.5 mg/kg. Participants will continue to receive mirvetuximab soravtansine (for clinical benefit) until unacceptable toxicity or withdrawal of consent, whichever comes first, or until the sponsor terminate the study.	Drug: Mirvetuximab soravtansine • Mirvetuximab soravtansine IV infusion will be administered as per dose and schedule specified in the respective arms. • Other Names: ◦ IMGN853
Experimental: Dose Expansion:EOC Participants(Mirvetuximab Soravtansine Q3W) Participants with epithelial ovarian cancer (EOC) will receive mirvetuximab soravtansine 6.0 mg/kg (maximum tolerated dose [MTD]) IV infusion on Day 1 of every 21-day (Q3W) cycle (calculated based on AIBW). Participants will continue to receive mirvetuximab soravtansine (for clinical benefit) until unacceptable toxicity or withdrawal of consent, whichever comes first, or until the sponsor terminated the study.	Drug: Mirvetuximab soravtansine • Mirvetuximab soravtansine IV infusion will be administered as per dose and schedule specified in the respective arms. • Other Names: ◦ IMGN853

Experimental: Dose Expansion: EC Participants(Mirvetuximab Soravtansine Q3W) Participants with endometrial cancer (EC) will receive mirvetuximab soravtansine 6.0 mg/kg (MTD) IV infusion on Day 1 of every 21-day (Q3W) cycle (calculated based on AIBW). Participants will continue to receive mirvetuximab soravtansine (for clinical benefit) until unacceptable toxicity or withdrawal of consent, whichever comes first, or until the sponsor terminate the study.	Drug: Mirvetuximab soravtansine • Mirvetuximab soravtansine IV infusion will be administered as per dose and schedule specified in the respective arms. • Other Names: ◦ IMGN853

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Dose-Escalation Phase: Maximum Tolerated Dose (MTD) of Mirvetuximab Soravtansine	MTD was defined as the highest dose at which 1 or fewer among 6 participants or less than or equal to (<=) 33 percent (%) experienced a dose-limiting toxicity (DLT) (calculated based on adjusted ideal body weight [AIBW]). AIBW was calculated as ideal body weight (IBW) + 0.4 * (actual weight - IBW), where IBW for men was 0.9 * height in centimeters (cm) - 88 and IBW for women was 0.9 * height in cm - 92. DLT was defined as a treatment-emergent adverse event (TEAE) or abnormal laboratory value related to study treatment (that is, assessed as unrelated to disease, intercurrent illness, or concomitant medications), including those TEAEs and abnormal laboratory values that resulted in a failure to meet the criteria for re-treatment.	Cycle 1 (21 days)
Dose-Escalation Phase: Recommended Phase 2 Dose (RP2D) of Mirvetuximab Soravtansine	RP2D was determined by MTD. MTD was defined as the highest dose at which 1 or fewer among 6 participants or <=33% experienced a DLT. DLT was defined as a TEAE or abnormal laboratory value related to study treatment (that is, assessed as unrelated to disease, intercurrent illness, or concomitant medications), including those TEAEs and abnormal laboratory values that resulted in a failure to meet the criteria for re-treatment. Available clinical data indicated that the MTD defined for the Q3W schedule was equal to the RP2D.	Cycle 1 (21 days)

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Number of Participants With TEAEs	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. Severity was graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.03 on following scale: Grade 1=mild, Grade 2=moderate, Grade 3=severe, Grade 4=life-threatening, Grade 5=death. Serious AEs include death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect, or an important medical event that jeopardized the participant and required medical intervention to prevent 1 of the outcomes listed in this definition. TEAEs were defined as any AE that emerged on or after the first dose, and within 28 days of the last dose.	From first dose of study drug up to 28 days after last dose of study drug (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-

		escalation Schedule B, 124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)
Number of Participants With Shift From Baseline Grade <=2 in Clinical Laboratory Parameters to Grade 3 or Grade 4 on Study	Laboratory parameters included serum chemistry (alanine aminotransferase [ALT]/serum glutamic pyruvic transaminase [SGPT], aspartate aminotransferase [AST]/serum glutamic oxaloacetic transaminase [SGOT], albumin, alkaline phosphatase, bilirubin, calcium, creatinine, glucose, magnesium, phosphorous, potassium, sodium), hematology (hemoglobin, lymphocytes, neutrophils, platelets, white blood cells) and coagulation (international normalized ratio [INR], partial thromboplastin time [PTT]). Clinically significant laboratory values were defined as per NCI CTCAE v.03 Grade 3 or higher. A grading (severity) scale was provided with grades ranging from 0 (none), 1 (mild), 2 (moderate), 3 (severe), 4 (life-threatening or disabling), to 5 (death). Only participants who shifted from a baseline value of Grade <=2 to a post-baseline Grade 3/4 on-treatment, are reported.	From first dose of study drug up to 28 days after last dose of study drug (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-escalation Schedule B, 124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)
Number of Participants With Clinically Significant Abnormalities in Physical Examination Findings and Vital Signs	Physical examination included assessments of general appearance, skin, head (eyes, ears, nose, and throat), neck, lungs, heart, abdomen, back, lymph nodes, extremities, and neurological system. Vital signs included assessment of blood pressure, pulse rate, respiratory rate and body temperature.	From first dose of study drug up to 28 days after last dose of study drug (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-escalation Schedule B, 124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)
Number of Participants With Clinically Significant Abnormalities in Electrocardiogram (ECG)	Standard ECGs were performed in triplicate at 2- to 5-minute intervals during the study. A single ECG was performed at the end of treatment visit and as clinically indicated.	Baseline up to end of treatment (EOT) (up to

		maximum 124 weeks)
Number of Participants With Treatment-Emergent Ocular AEs	Ocular AEs included keratopathy and blurred vision. An 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 any AE that emerged on or after the first dose, and within 28 days of the last dose.	From first dose of study drug up to 28 days after last dose of study drug (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-escalation Schedule B, 124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)
Maximum Observed Plasma Concentration (Cmax) of Mirvetuximab Soravtansine and Total M9346A Antibody at RP2D	Pharmacokinetic (PK) parameters were calculated using standard non-compartmental methods. PK analysis of mirvetuximab soravtansine and total M9346A antibody is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 minutes [min] of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8, 15 (24 hrs post-infusion)
Cmax of Free DM4 and S-Methyl DM4 at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of free N2'-[4-[(3-carboxypropyl)dithio]-4-methyl-1-oxo-2-sulfopentyl]-N2'-deacetylmaytansine (DM4) and S-methyl DM4 is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8, 15 (24 hrs post-infusion)
Area Under the Plasma Concentration-Time Curve Extrapolated to Infinity (AUC0-inf) of Mirvetuximab Soravtansine and Total M9346A Antibody at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of mirvetuximab soravtansine and total M9346A antibody is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8,

		15 (24 hrs post-infusion)
AUC0-inf of Free DM4 and S-Methyl DM4 at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of free DM4 and S-methyl DM4 is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8, 15 (24 hrs post-infusion)
Area Under the Plasma Concentration-Versus Time Curve From Time of Dose Until Tlast (AUClast) of Mirvetuximab Soravtansine and Total M9346A Antibody at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of mirvetuximab soravtansine and total M9346A antibody is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8, 15 (24 hrs post-infusion)
AUClast of Free DM4 and S-Methyl DM4 at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of free DM4 and S-methyl DM4 is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8, 15 (24 hrs post-infusion)
Terminal Half-Life (t1/2) of Mirvetuximab Soravtansine,Total M9346A Antibody, DM4, and S-Methyl DM4 at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of mirvetuximab soravtansine, total M9346A antibody, DM4, and S-methyl DM4 is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8, 15 (24 hrs post-infusion)
Clearance (CL) of Mirvetuximab Soravtansine and Total M9346A Antibody at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of mirvetuximab soravtansine and total M9346A antibody is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8,

		15 (24 hrs post-infusion)
CL of DM4 and S-Methyl DM4 at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of DM4 and S-methyl DM4 is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8, 15 (24 hrs post-infusion)
Time to Reach Maximum Observed Concentration (Tmax) of Mirvetuximab Soravtansine, Free DM4, S-Methyl DM4, and Total M9346A Antibody at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of mirvetuximab soravtansine, free DM4, S-methyl DM4, and total M9346A antibody is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8, 15 (24 hrs post-infusion)
Volume of Distribution at Steady State (Vss) of Mirvetuximab Soravtansine Free DM4, S-Methyl DM4, and Total M9346A Antibody at RP2D	PK parameters were calculated using standard non-compartmental methods. PK analysis of mirvetuximab soravtansine, free DM4, S-methyl DM4, and total M9346A antibody is presented for a subgroup of participants who received 6.0 mg/kg (RP2D) mirvetuximab soravtansine at Cycle 1 and Cycle 3.	Cycle 1, 3: Day 1 (pre-infusion; within 10 min of EOI; 2, 4, 6, 8 hrs post-infusion); Day 2, 3 (24, 48 hrs post-infusion); Day 4 or 5, 8, 15 (24 hrs post-infusion)
Objective Response Rate (ORR): Percentage of Participants With Objective Response as Assessed by Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)	ORR was defined as percentage of participants with a 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 less than (<) 10 millimeters (mm). PR: At least 30 percent (%) decrease in the sum of the longest diameters (SoD) of target lesions, taking as reference the baseline SoD.	From first dose of study drug until first BOR of CR or PR (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-escalation Schedule B, 124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)

Duration of Response (DOR) as Assessed by RECIST v1.1	DOR was defined as the time from the date of the first response (CR or PR), whichever was recorded first, until the date of progressive disease (PD). 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 only defined for participants who had a BOR of CR or PR using the method of Kaplan-Meier.	From the date of first response (CR or PR) until the date of PD (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-escalation Schedule B, 124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)
Progression-Free Survival (PFS) as Assessed by RECIST v1.1	PFS was defined as the time from initiation of study drug until 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.	From first dose of study drug until PD or death whichever occurred first (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-escalation Schedule B, 124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)
Time to Progression (TTP) as Assessed by RECIST v1.1	TTP was defined as the time from initiation of study drug until PD, estimated using the method of Kaplan-Meier. 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.	From first dose of study drug until PD (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-escalation Schedule B,

		124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)
Number of Participants With Anti-Drug Antibodies (ADA)	During the conduct of the study, a single immunogenicity assay was developed to concurrently detect human antibodies against all components of mirvetuximab soravtansine, including the humanized anti-FOLR1 antibody, the cleavable disulfide linker, and the cytotoxic maytansinoid, DM4. Therefore, immunogenicity results were reported as ADA titers, and did not distinguish between human anti-drug or anti-human titers.	Baseline up to follow-up visit (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-escalation Schedule B, 124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)
Number of Participants With Gynecologic Cancer Intergroup (GCIG) CA-125 Criteria Clinical Responses	CA-125 response was defined as at least 50% reduction in CA-125 levels from baseline. The date of response corresponded to the date when the CA 125 level was first reduced by 50%.	From first dose of study drug until CA-125 response (maximum exposure: 36 weeks for dose-escalation Schedule A, 101.3 weeks for dose-escalation Schedule B, 124 weeks for dose-expansion EOC, 33.3 weeks for dose-expansion EC)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

ImmunoGen, Inc.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted
2012-05-30

First Submitted that Met QC Criteria
2012-05-31

First Posted (Estimated)
2012-06-01

Results Reporting Dates

Results First Submitted
2019-02-01

Results First Submitted that Met QC Criteria
2021-01-27

Results First Posted
2021-02-17

Study Record Updates

Last Update Submitted that met QC Criteria
2021-01-27

Last Update Posted
2021-02-17

Last Verified
2021-01

More Information

Terms related to this study

Keywords Provided by ImmunoGen, Inc.

FOLR-1 solid tumors

Additional Relevant MeSH Terms

Immunoconjugates
Immunologic Factors
Physiological Effects of Drugs
Antineoplastic Agents, Phytogenic
Antineoplastic Agents
Tubulin Modulators
Antimitotic Agents
Mitosis Modulators
Molecular Mechanisms of Pharmacological Action
Maytansine
Mirvetuximab soravtansine

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

No

Study Documents Provided by ImmunoGen, Inc.

- Study Protocol (https://cdn.clinicaltrials.gov/large-docs/56/NCT01609556/Prot_000.pdf) [PDF, 1.48MB, 2015-09-02]
- Statistical Analysis Plan (https://cdn.clinicaltrials.gov/large-docs/56/NCT01609556/SAP_001.pdf) [PDF, 0.82MB, 2018-02-01]