UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 29, 2019

ImmunoGen, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts	**0-17999**	**04-2726691**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

830 Winter Street, Waltham, MA 02451
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 895-0600

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, $.01 par value	IMGN	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

As previously announced, ImmunoGen, Inc. (also referred to as "we") will host an investor conference call on September 30, 2019 at 8:00 a.m., ET, to discuss the data from the FORWARD I study referenced in Item 8.01 below. A copy of the investor presentation to be used on the investor conference call is being furnished with this Current Report on Form 8-K as Exhibit 99.3.

Item 8.01 Other Events

On September 29, 2019, we issued a press release summarizing the full data and additional exploratory analyses from the Phase 3 FORWARD I study evaluating mirvetuximab soravtansine compared to chemotherapy in women with folate receptor alpha (FRα)-positive, platinum-resistant ovarian cancer which was presented on September 29, 2019 at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain. A copy of such press release is being filed with this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

On September 29, 2019, we also issued a separate press release summarizing the initial safety and overall response data from the Phase 1b FORWARD II triplet cohort evaluating mirvetuximab in combination with carboplatin and Avastin® (bevacizumab) in patients with recurrent, platinum-sensitive ovarian cancer which was presented on September 29, 2019 at the ESMO 2019 Congress. A copy of such press release is being filed with this Current Report on Form 8-K as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d): Exhibits

Exhibit No.	Exhibit
99.1	Press Release of ImmunoGen, Inc. for FORWARD I dated September 29, 2019
99.2	Press Release of ImmunoGen, Inc. for FORWARD II dated September 29, 2019
99.3	Investor presentation to be presented by ImmunoGen, Inc. on September 30, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL (eXtensible Business Reporting Language) document)

The information set forth in Exhibit 99.2 shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ImmunoGen, Inc.
(Registrant)

Date: September 30, 2019

/s/ David G. Foster

David G. Foster
Vice President, Finance

Exhibit 99.1

ImmunoGen Presents Full Data from Phase 3 FORWARD I Study of Mirvetuximab Soravtansine in Ovarian Cancer at ESMO

FORWARD I Did Not Meet Primary Endpoint of Progression-Free Survival; Promising Efficacy Results Seen in Folate Receptor Alpha (FRα) High Patients

Favorable Tolerability and Differentiated Safety Profile Observed with Mirvetuximab Monotherapy Compared to Chemotherapy

Exploratory Analyses Demonstrate Improved Efficacy Outcomes in FRα High Patients

Registration Study for Mirvetuximab in Ovarian Cancer on Track to Start by Year-End

Conference Call to be Held Monday, September 30 at 8:00 a.m. ET

WALTHAM, MA - September 29, 2019 – ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced full data and additional exploratory analyses from the Phase 3 FORWARD I study evaluating mirvetuximab soravtansine compared to chemotherapy in women with folate receptor alpha (FRα)-positive, platinum-resistant ovarian cancer during an oral presentation at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain.

“While it is disappointing that FORWARD I did not meet the primary endpoint of progression-free survival, mirvetuximab demonstrated consistent and meaningful efficacy signals in patients with high levels of FRα expression and was well tolerated with a differentiated safety profile in both the ITT and FRα high populations,” said Dr. Kathleen Moore, Associate Director of Clinical Research at the Stephenson Cancer Center at the University of Oklahoma. “Despite recently reported advances in frontline treatment with the addition of PARPi maintenance therapy, the majority of patients will unfortunately develop platinum-resistant disease with limited therapeutic options characterized by low response rates, short progression-free survival, and significant toxicities. The encouraging data from FORWARD I suggest the potential for a significant improvement over single-agent chemotherapy in the FRα high population and I look forward to the continued development of mirvetuximab for these patients in the upcoming Phase 3 study.”

The FORWARD I Phase 3 trial randomized 366 patients 2:1 to receive either mirvetuximab or the physician's choice of single-agent chemotherapy (pegylated liposomal doxorubicin, topotecan, or weekly paclitaxel). Eligibility criteria included patients with platinum-resistant ovarian cancer that expressed medium or high levels of FRα, who had been treated with up to three prior regimens. The primary endpoint of this study was progression-free survival (PFS), which was assessed using the Hochberg procedure in the entire study population and in the subset of patients with high FRα expression. The Hochberg procedure enables the simultaneous testing of two overlapping populations. Under this statistical analysis plan, if the p-value of the primary endpoint in either population is greater than 0.05, the p-value in the other population needs to be less than or equal to 0.025 to achieve statistical significance.

Key Findings from the Phase 3 FORWARD I Study

- In the entire study population, the confirmed overall response rate (ORR) was higher for mirvetuximab than for chemotherapy (22% vs 12%, p-value 0.015), without a significant difference in the primary endpoint of PFS (HR 0.981, p-value 0.897) or overall survival (OS) (HR 0.815, p-value 0.248).
- In the pre-specified FRα high subgroup (218/366, 60%):
    - Median PFS (mPFS) was longer in patients who received mirvetuximab compared with chemotherapy (4.8 months vs 3.3 months, HR 0.693, p-value 0.049). Given that the p-value in the entire study population exceeded 0.05, the statistical analysis plan for the study required

the p-value in the high subset to be less than or equal to 0.025 to achieve statistical significance.
    - Confirmed ORR was higher for mirvetuximab than for chemotherapy (24% vs 10%, p-value 0.014).
    - OS was longer in patients who received mirvetuximab compared with chemotherapy (HR 0.618, p-value 0.033).
    - The trend in improved OS in patients who received mirvetuximab compared with chemotherapy persisted with an additional 6 months of follow-up (updated through August 2019: HR 0.678, with median OS [mOS] 16.4 months vs 12.0 months, p-value 0.048).
- Mirvetuximab was well-tolerated, with fewer patients experiencing grade 3 or greater treatment emergent adverse events (TEAEs) (46% vs 61%), fewer dose reductions (20% vs 31%), and fewer discontinuations due to drug-related TEAEs (5% vs 8%) compared with chemotherapy.
- The safety profile of mirvetuximab was confirmed, with the most common drug-related adverse events including nausea (46% all grades; 1% grade 3 or greater), blurred vision (42% all grades; 2% grade 3 or greater), and keratopathy (33% all grades; 1% grade 3 or greater).
- Over twice the percentage of patients who received mirvetuximab compared with chemotherapy reported improved quality of life, as measured by at least a 15-point improvement in the abdominal/GI symptom subscale of the EORTC-QLQ OV28 (32% vs 14%).

Exploratory Analyses

“While FORWARD I generated promising outcomes in the FRα high subgroup, the anti-tumor activity did not reach the levels we have observed in our previous studies with mirvetuximab. Accordingly, we have undertaken a comprehensive assessment of the factors that may have contributed to the outcomes in FORWARD I. These exploratory analyses demonstrate that the use of a simplified scoring method to assess tumor samples for FRα expression inadvertently introduced a population of patients into FORWARD I with lower levels of FRα than intended,” said Anna Berkenblit, M.D., Senior Vice President and Chief Medical Officer of ImmunoGen. “When we reassessed the FORWARD I tumor samples using the scoring method from our previous studies, we determined that a significant percentage of patients included in FORWARD I had low levels of FRα expression that should have precluded enrollment. For those patients with medium or high levels of FRα expression upon rescoring, we observed efficacy outcomes for mirvetuximab much more in line with our previous experience, with improved activity correlating with FRα expression and the strongest treatment effect for all efficacy endpoints in the intended FRα high patient population. These findings have informed the design of our planned Phase 3 registration trial in FRα high patients.”

Previous studies with mirvetuximab have used a PS2+ scoring method to assess tumor samples for FRα expression to determine eligibility. The PS2+ scoring method assesses both intensity of staining (0, 1+, 2+, or 3+) and percentage of tumor cells staining at each intensity, with at least 50% of cells with at least 2+ staining considered FRα medium and at least 75% of cells with at least 2+ staining considered FRα high.

In preparation for launch of a companion diagnostic for commercial use, a simplified scoring method to assess FRα expression, known as 10X, was implemented prior to the start of FORWARD I. Eligibility was determined by scoring the percentage of tumor cells with positive membrane staining by ≤10X magnification without the need to separately assess level of intensity. A bridging study indicated that the 10X scoring method was sufficient for patient selection: staining visible at ≤10X magnification correlated with higher intensity staining (2+ and 3+), with lower intensity staining visible only at higher magnification.

Comparison to the much larger dataset from patients enrolled in FORWARD I, however, suggested a significant population shift towards increased prevalence of FRα expression under the 10X scoring method as compared to the PS2+ scoring method. Rescoring of the FORWARD I tumor samples by an independent pathologist, blinded to treatment assignment, using the PS2+ method demonstrated that 34% of patients enrolled in FORWARD I had FRα expression below the intended level. In addition, the FRα high subset enrolled in the study also contained a mixture of FRα expression when scored using the PS2+ method.

Key Findings from Exploratory PS2+ Scoring for FRα Determination in Phase 3 FORWARD Study

Exploratory efficacy analyses of the FORWARD I patients scored using the PS2+ method demonstrate improved outcomes correlated with FRα expression, with the strongest treatment effects for all efficacy endpoints in the PS2+ FRα high population (n=116). Compared with chemotherapy, mirvetuximab was associated with:

- Longer PFS (mPFS 5.6 months vs 3.2 months, HR 0.549 [95% CI 0.336, 0.897]);
- Higher confirmed ORR (29% vs 6%); and
- Longer OS (updated through August 2019: mOS 16.4 months vs 11.4 months, HR 0.678 [95% CI 0.410, 1.119]).

"With the results of these exploratory analyses, we have developed a clear view of which patients benefit most from mirvetuximab and how to best identify those patients," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "We are working closely with FDA to finalize the design of a Phase 3 registration trial for mirvetuximab, which we call MIRASOL, and believe that the robust data generated from the FORWARD I analyses increase the likelihood of a positive outcome with this next study. We anticipate enrolling the first patient by the end of the year with topline readout in the first half of 2022."

ESMO Oral Presentation Details

- **Title:** "FORWARD I (GOG 3011): A Phase III study of mirvetuximab soravtansine, a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC), versus chemotherapy in patients (pts) with platinum-resistant ovarian cancer (PROC)" (Abstract #992O)
- **Date:** Sunday, September 29, 2019
- **Time:** 8:30 a.m. CEST/2:30 a.m. ET
- **Lead Author:** Kathleen Moore M.D., University of Oklahoma Health Sciences Center, Oklahoma City, OK

Additional information can be found at www.esmo.org.

CONFERENCE CALL INFORMATION

ImmunoGen will host a conference call on Monday, September 30, 2019 at 8:00 a.m. ET to discuss the complete findings from FORWARD I. Access the call using the information below.

PHONE
US Toll-Free: (877) 621-5803
Spain Toll-Free: 900971520
Barcelona Local: 0934923253
International: (470) 495-9491
Conference ID: 8295336

SLIDES/WEBCAST
Link: https://edge.media-server.com/mmc/p/jwvdobji

ABOUT MIRVETUXIMAB SORAVTANSINE

Mirvetuximab soravtansine (IMGN853) is the first folate receptor alpha (FRα)-targeting ADC. It uses a humanized FRα-binding antibody to target the ADC specifically to FRα-expressing cancer cells and a potent anti-tumor agent, DM4, to kill the targeted cancer cells.

ABOUT FORWARD I

FORWARD I is a Phase 3 trial in which 366 patients were randomized 2:1 to receive either mirvetuximab soravtansine or the physician's choice of single-agent chemotherapy (pegylated liposomal doxorubicin, topotecan, or weekly paclitaxel). Eligible patients were diagnosed with platinum-resistant ovarian cancer that expresses medium or high levels of folate receptor alpha (FRα) and were treated with up to three prior regimens. The primary endpoint of this study was progression free survival (PFS), which was assessed in the entire study population and in the subset of patients with high FRα expression. ImmunoGen estimates that 12,000-14,000 patients per year in the U.S. meet these criteria, with a comparable number in the major markets in Europe.

ImmunoGen partnered with the GOG Foundation Inc., a leader in clinical research in gynecologic malignancies, on FORWARD I, which was conducted in North America and Europe.

ABOUT IMMUNOGEN

ImmunoGen is developing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer our patients more good days. We call this our commitment to "target a better now."

Learn more about who we are, what we do, and how we do it at www.immunogen.com.

This press release includes forward-looking statements regarding ImmunoGen's expectations related to: the design and potential success of ImmunoGen's future mirvetuximab soravtansine studies and regulatory pathway, including the timing of initiating and receiving data from, as well as the likelihood of success of, the planned registration study of mirvetuximab. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and results of communications with FDA, risks and uncertainties related to the execution of the restructuring of the Company's operations, the Company's ability to control future spending and obtain additional funds to enable it to fund its continuing operations through the release of top-line results from the planned mirvetuximab pivotal study, the possibility that future studies fail to replicate the data indicated in the exploratory analyses of the FORWARD 1 data, and the risks and uncertainties inherent in the Company's development programs, including clinical studies and regulatory processes, their timings and results. A review of these risks can be found under the heading "Risk Factors" in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2018 and subsequent documents filed with the Securities and Exchange Commission.

INVESTOR RELATIONS AND MEDIA

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Exhibit 99.2

ImmunoGen Presents Initial Data from Phase 1b FORWARD II Triplet Cohort Evaluating Mirvetuximab Soravtansine in Combination with Carboplatin and Avastin® at ESMO

FORWARD II Triplet Combination Demonstrates Encouraging Anti-Tumor Activity

Preliminary Findings Support Ongoing Study in Platinum-Sensitive Patients

WALTHAM, MA - September 29, 2019 – ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced initial safety and overall response data from the Phase 1b FORWARD II triplet cohort evaluating mirvetuximab in combination with carboplatin and Avastin® (bevacizumab) in patients with recurrent, platinum-sensitive ovarian cancer at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain.

“The initial results from the triplet combining mirvetuximab with both bevacizumab and carboplatin build nicely off of the encouraging data previously generated when mirvetuximab was paired individually with each of these agents,” said David O'Malley, M.D., Professor, Director of Gynecologic Oncology and Co-Director, Gynecologic Oncology Phase 1 Program at The Ohio State University and the James Cancer Center, and FORWARD II Principal Investigator. “The anti-tumor responses observed with this combination compare favorably to those of other triplets and I look forward to reporting longer-term efficacy data, as we seek to provide new treatment options for patients with recurrent, FRα-positive platinum-sensitive ovarian cancer.”

Key Findings from FORWARD II Triplet Cohort

- In 41 patients with recurrent platinum-sensitive disease with medium or high folate receptor alpha (FRα) expression levels who have received up to two prior lines of therapy, the confirmed overall response rate (ORR) for the triplet was 83%, with a complete response (CR) rate of 17%.
- In a subset of 31 patients with only 1 prior line, the confirmed ORR was 90%, with a CR rate of 19%.
- These efficacy outcomes are encouraging relative to those reported in similar patient populations for other carboplatin and bevacizumab-based triplets.
- With a median follow up of 9.3 months, progression-free survival (PFS) data are maturing.
- The combination of full dose mirvetuximab, carboplatin and bevacizumab is well tolerated.
- No new safety signals were seen; adverse events observed with the triplet were as expected based on the side effect profiles of each agent, with thrombocytopenia as the most common cause of drug-related discontinuations.
- Post-carboplatin (median 6 cycles), mirvetuximab and bevacizumab continuation/maintenance is well tolerated.

“We are encouraged by the initial safety and overall response data from our triplet cohort, demonstrating that full-dose mirvetuximab can be combined safely with the standard dosing for both bevacizumab and carboplatin,” said Anna Berkenblit, M.D., Vice President and Chief Medical Officer of ImmunoGen. “We are continuing to follow patients for progression-free survival and look forward to initiating the next set of studies to support a path to registration in platinum-sensitive ovarian cancer.”

ESMO Poster Details

- **Title:** “Mirvetuximab soravtansine, a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC), in combination with carboplatin and bevacizumab: Initial results from a Phase 1b study in patients with ovarian cancer” (Abstract #1028P)
- **Date:** Sunday, September 29, 2019
- **Time:** 12:00 p.m. CEST/6:00 a.m. EDT

- **Lead Author:** David M. O'Malley M.D., James Comprehensive Cancer Center, The Ohio State University, Columbus, OH

Additional information can be found at www.esmo.org.

ABOUT MIRVETUXIMAB SORAVTANSINE
Mirvetuximab soravtansine (IMGN853) is the first folate receptor alpha (FRα)-targeting ADC. It uses a humanized FRα-binding antibody to target the ADC specifically to FRα-expressing cancer cells and a potent anti-tumor agent, DM4, to kill the targeted cancer cells.

ABOUT FORWARD II
FORWARD II is a Phase 1b/2 study of mirvetuximab soravtansine in combination with AVASTIN® (bevacizumab) in patients with platinum-resistant ovarian cancer that express medium or high levels of FRα as well as a triplet combination of mirvetuximab plus carboplatin and bevacizumab in patients with platinum-sensitive ovarian cancer that express medium or high levels of FRα.

ABOUT IMMUNOGEN
ImmunoGen is developing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer our patients more good days. We call this our commitment to "target a better now."

Learn more about who we are, what we do, and how we do it at www.immunogen.com.

AVASTIN® is a registered trademark of Genentech, Inc.

This press release includes forward-looking statements based on management's current expectations. These statements include, but are not limited to, ImmunoGen's expectations related to: obtaining PFS data for the triplet cohort and the initiation of the next studies to support a path to registration of the triplet therapy in platinum-sensitive ovarian cancer. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and results of communications with FDA, risks and uncertainties related to the execution of the restructuring of the Company's operations, the Company's ability to control future spending and raise additional funds to enable it to fund its continuing operations through the release of top-line results from the planned mirvetuximab pivotal study, the possibility that futures studies fail to replicate the data indicated in the exploratory analyses of the FORWARD I data, and the risks and uncertainties inherent in the Company's development programs, including clinical studies and regulatory processes, their timings and results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2018 and other reports filed with the Securities and Exchange Commission.

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Exhibit 99.3

FORWARD I: Full Data and Exploratory Analyses

30 September 2019

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FORWARD LOOKING STATEMENTS

This presentation includes forward-looking statements regarding ImmunoGen's expectations related to: the design and potential success of ImmunoGen's future mirvetuximab soravtansine studies and regulatory pathway, including the timing of initiating and receiving data from, as well as the likelihood of success of, the planned registration study of mirvetuximab. For these statements, ImmunoGen claims the protection of the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this presentation. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and results of communications with FDA, risks and uncertainties related to the execution of the restructuring of the Company's operations, the Company's ability to control future spending and obtain additional funds to enable it to fund its continuing operations through the release of top-line results from the planned mirvetuximab pivotal study, the possibility that future studies fail to replicate the data indicated in the exploratory analyses of the FORWARD 1 data, and the risks and uncertainties inherent in the Company's development programs, including clinical studies and regulatory processes, their timings and results. A review of these risks can be found under the heading "Risk Factors" in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2018 and subsequent documents filed with the Securities and Exchange Commission.

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Agenda

1. Overview
2. FORWARD I
3. Closing Remarks
4. Q&A with Dr. Kathleen Moore

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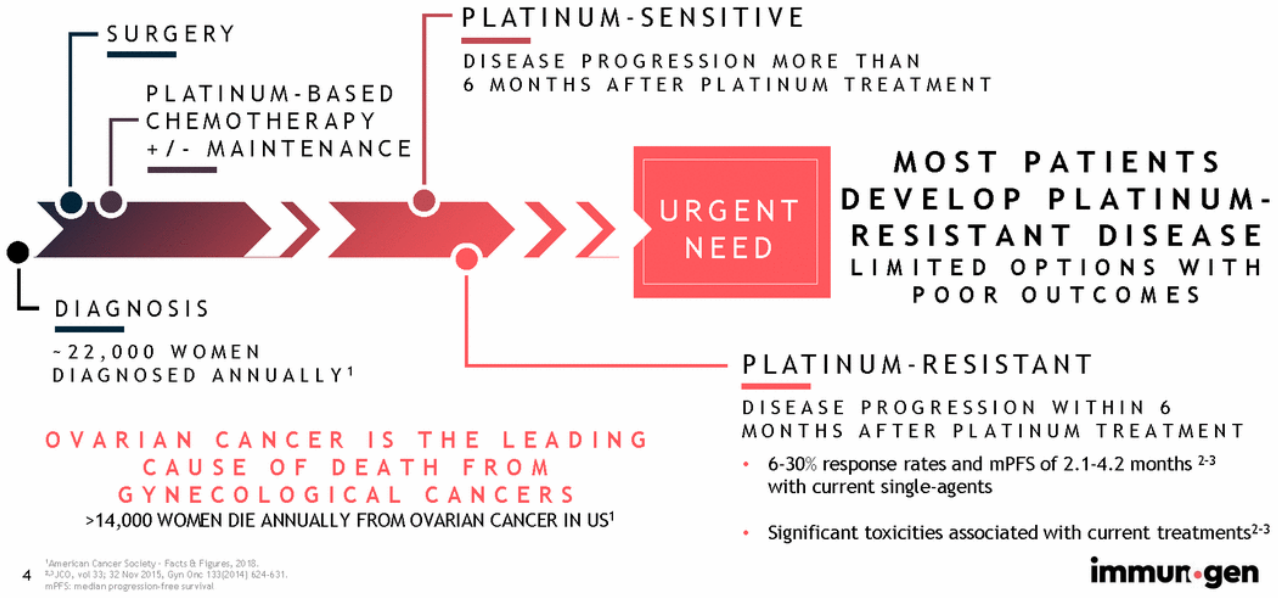
Ovarian Cancer Landscape



OVARIAN CANCER IS THE LEADING CAUSE OF DEATH FROM GYNECOLOGICAL CANCERS

>14,000 WOMEN DIE ANNUALLY FROM OVARIAN CANCER IN US[1]

[1]American Cancer Society - Facts & Figures, 2018.
[2]JCO, vol 33; 32 Nov 2015, Gyn Onc 133(2014) 624-631.
mPFS: median progression-free survival

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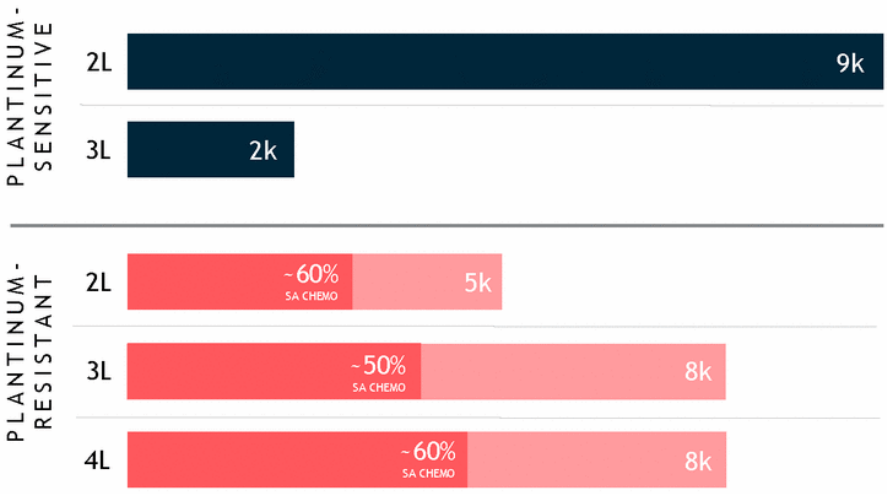
Mirvetuximab Soravtansine

First Indication and Ongoing Expansion Studies Will Cover Significant Percentage of Recurrent Ovarian Cancer Patients



EXPANDED INDICATIONS
~8,000 PATIENTS
FRα HIGH

FIRST INDICATION
~5,000 PATIENTS
FRα HIGH

*Numbers represent drug treatable US patients.
Sources: Decision Resources Group; Diagnosed drug-treatable patients 2017. Kantar Health. Ipsos Oncology Monitor, 2018 and 2019.

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Mirvetuximab: Monotherapy Summary and Next Steps

FORWARD I

- Trial did not meet primary endpoint of progression-free survival
- Consistent efficacy signal seen in folate receptor alpha (FRα) high patients
- Favorable tolerability profile confirmed

Exploratory Analyses

- Change in scoring method from PS2+ to 10X introduced a population of patients into FORWARD I with lower levels of FRα expression than intended
- Analyses of patients scored using PS2+ demonstrate improved outcomes correlated with FRα expression
- Strongest treatment effect for all efficacy endpoints observed in FRα high population

Registration Study

- Data from FORWARD I inform patient selection and significantly improve the likelihood of a positive outcome
- New Phase 3 trial in FRα high patients expected to begin by the end of 2019

MIRASOL

immunogen

FORWARD I

Anna Berkenblit
Senior Vice President and Chief Medical Officer

immunogen

FORWARD I: STUDY DESIGN

Key Eligibility

- Platinum-resistant ovarian cancer
- FRα-positive tumor expression
  - Medium (50-74% cells positive)
  - High (≥75% cells positive)
- ECOG performance status 0 or 1
- 1-3 prior therapies

Statistical Assumptions

- Hochberg Procedure
- α=0.05 (two-sided), Power = 90%, HR=0.58; control arm mPFS 3.5 mos

Mirvetuximab Soravtansine
(n=248)

6 mg/kg (adjusted ideal body weight) once every 3 weeks

2:1 Randomization

Stratification Factors:
FRα expression (medium or high)
Prior therapies (1 and 2, or 3)
Choice of chemotherapy

Investigator's Choice Chemotherapy
Paclitaxel, PLD†, or Topotecan
(n=118)

Paclitaxel: 80 mg/m² weekly
PLD: 40 mg/m² once every 4 weeks
Topotecan: 4 mg/m² on Days 1, 8, and 15 every 4 weeks; or 1.25 mg/m² on Days 1-5 every 3 weeks

Primary Endpoint

Progression-free survival (PFS; by BIRC*) for ITT and FRα high populations

Secondary Endpoints

Overall response rate (ORR)
Overall survival (OS)
Patient reported outcomes (PRO)

*BIRC = Blinded Independent Review Committee; analyzed by Hochberg procedure
†PLD = pegylated liposomal doxorubicin

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Baseline Characteristics

DISEASE CHARACTERISTICS

	Mirvetuximab soravtansine (n=248)	IC Chemo (n=118)
Primary Diagnosis		
Ovarian	83%	89%
Fallopian Tube	6%	4%
Primary Peritoneal	11%	7%
Histology		
High Grade Serous	99%	97%
Other	1%	3%
ECOG		
0	57%	51%
1	43%	48%
Prior Therapy		
Bevacizumab	49%	47%
PARPi	11%	10%
Any BRCA Mutation		
Yes	9%	7%
Platinum-Free Interval		
0-3 months	39%	38%
3-6 months	57%	58%
≥ 6 months	4%	4%

STRATIFICATION FACTORS

	Mirvetuximab soravtansine (n=248)	IC Chemo (n=118)
FRα Status		
Medium	42%	42%
High	58%	58%
No. Prior Lines		
1 or 2	65%	65%
3	35%	35%
IC Chemotherapy		
Paclitaxel	32%	31%
PLD	44%	46%
Topotecan	23%	23%

BASELINE CHARACTERISTICS WELL BALANCED

CHOICE OF CHEMOTHERAPY REFLECTS REAL-WORLD USAGE

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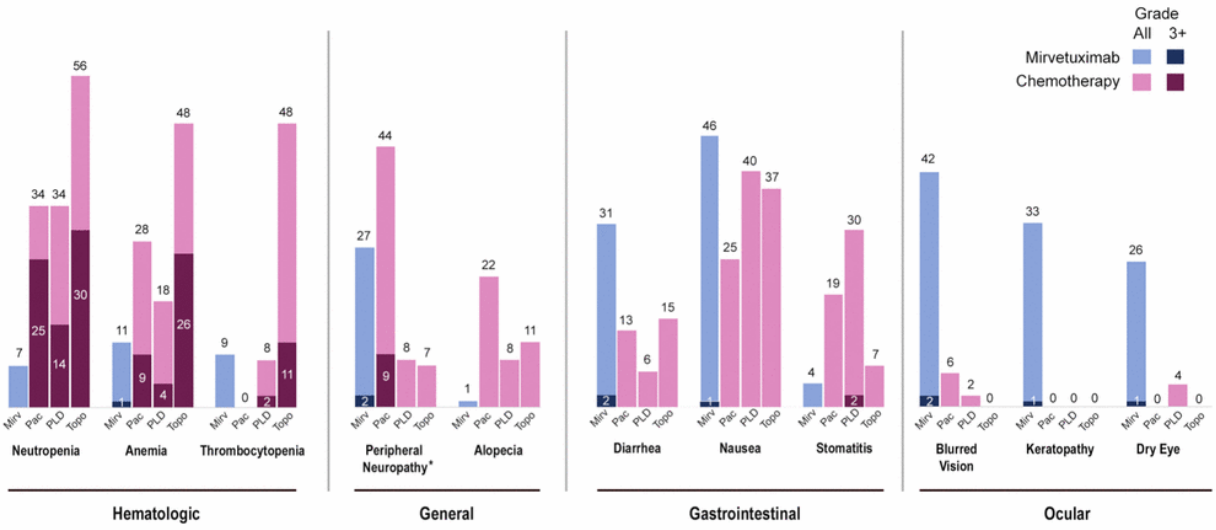
Safety Summary

MIRVETUXIMAB WAS WELL TOLERATED, WITH A DIFFERENTIATED SAFETY PROFILE, FEWER GRADE 3+ AEs, AND FEWER DRUG-RELATED DOSE REDUCTIONS/DISCONTINUATIONS

	Mirvetuximab soravtansine (n=243*)	IC Chemotherapy (n=109*)
Any TEAE	>99%	98%
Grade 3+ TEAEs	46%	61%
SAEs	28%	28%
Deaths on study drug or within 30 days of last dose	4%	6%
Dose reductions due to related TEAEs	20%	30%
Dose delays due to related TEAEs	29%	28%
Discontinuations due to related TEAEs	5%	8%

*Five and nine patients randomized into the mirvetuximab soravtansine and chemotherapy arms, respectively, did not receive any allocated intervention and were not included in the safety analyses

Most Common Treatment-Related Adverse Events (>20%): Differentiated Safety Profile



*Grade 2+ Peripheral neuropathy events were observed in 12% and 28% of patients that received mirvetuximab or paclitaxel, respectively

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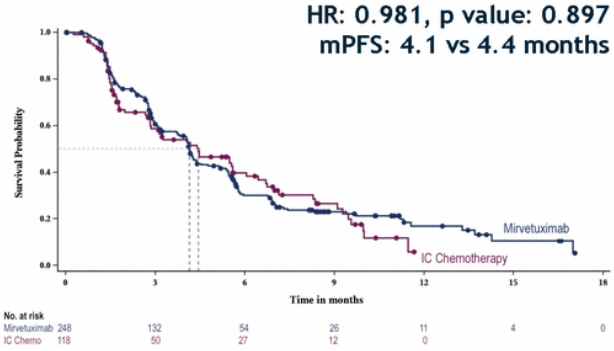
Primary Endpoint: Progression-Free Survival (By BIRC)

FORWARD I DID NOT MEET PRIMARY ENDPOINT

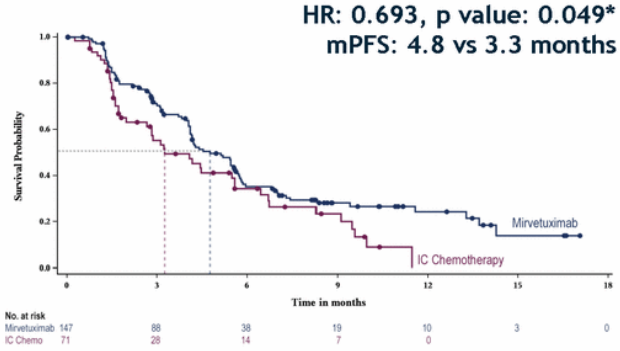
ITT POPULATION

HR: 0.981, p value: 0.897
mPFS: 4.1 vs 4.4 months



FRα HIGH POPULATION

HR: 0.693, p value: 0.049*
mPFS: 4.8 vs 3.3 months



*Not significant per Hochberg procedure

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Efficacy Results

CONSISTENT EFFICACY SIGNAL IN THE FRα HIGH POPULATION

ITT POPULATION

Endpoint	Treatment effect size [Mirv (n=248) vs IC Chemo (n=118)]	P value*
PFS by BIRC (mo.)	HR: 0.981 (0.734, 1.310) mPFS: 4.1 vs 4.4	0.897^
ORR by BIRC 95% CIs	22% vs 12% (17%, 28%) vs (7%, 19%)	0.015
OS (mo.)	HR: 0.815 (0.575, 1.154) mOS: 16.4 vs 14.0	0.248
OS (*August 2019*) (mo.)	HR: 0.846 (0.625, 1.145) mOS: 15.6 vs 13.9	0.278
PRO†	32% vs 14%	0.011

FRα HIGH POPULATION

Endpoint	Treatment effect size [Mirv (n=147) vs IC Chemo (n=71)]	P value*
PFS by BIRC (mo.)	**HR: 0.693** (0.480, 1.000) **mPFS: 4.8 vs 3.3**	0.049^
ORR by BIRC 95% CIs	**24% vs 10%** (17%, 32%) vs (4%, 19%)	0.014
OS (mo.)	HR: 0.618 (0.395, 0.966) mOS: NR vs 11.8	0.033
OS (*August 2019*) (mo.)	**HR: 0.678** (0.460, 0.999) **mOS: 16.4 vs 12.0**	0.048
PRO†	**28% vs 13%**	0.096

*Nominal p-value
^Not significant based on Hochberg Procedure
†≥15-point improvement in the EORTC QLQ-OV28 Abdominal/GI Symptom Subscale
NR = not reached
Unless otherwise noted, data cut January 2019

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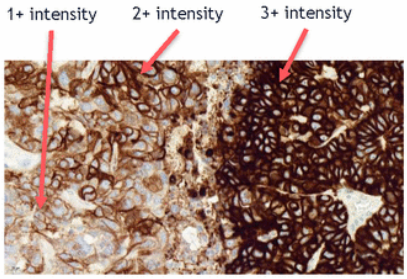
FRα Scoring in the Mirvetuximab Soravtansine Program

PS2+ SCORING

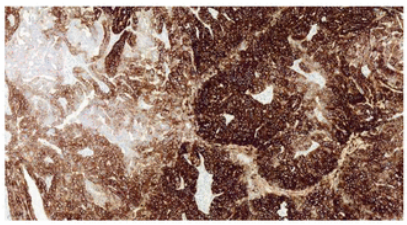
- In all prior studies, PS2+ scoring was used to assess FRα expression
- Eligibility determined by scoring intensity and percentage of tumor cells staining at 0, 1+, 2+, or 3+

PS2+ SCORING POSITIVE:
≥ 50% of tumor cells with FRα membrane staining with ≥ 2+ intensity



10X SCORING

- In FORWARD I, a simplified scoring method to assess FRα expression was implemented
- Eligibility was determined by scoring just the percentage of cells with membrane staining by ≤10X magnification, without the need to separately assess the level of intensity



10X SCORING POSITIVE:
≥ 50% of tumor cells with FRα membrane staining visible at 10X microscope objective

BRIDGING STUDY INDICATED THAT 10X SCORING WAS SUFFICIENT FOR PATIENT SELECTION
EXPLORATORY ANALYSES SUGGEST THAT THE CHANGE IN SCORING METHOD FROM PS2+ TO 10X INTRODUCED A POPULATION OF PATIENTS INTO FORWARD I WITH LOWER LEVELS OF FRα EXPRESSION THAN INTENDED

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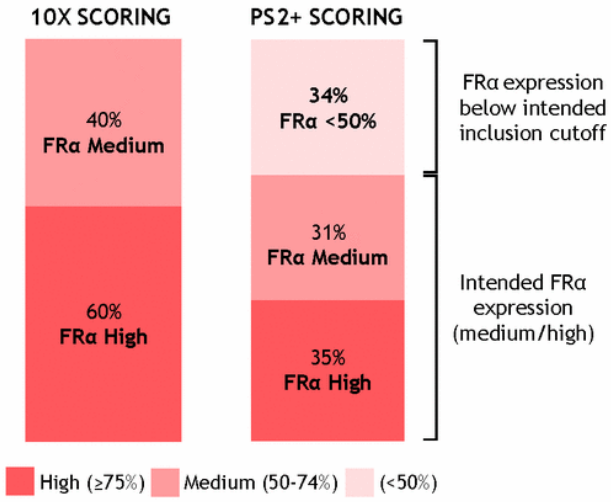
FORWARD I 10X Scoring Compared with Exploratory PS2+ Scoring (n=333)

Rescoring of the FORWARD I samples using PS2+ indicates:

- 34% of patients enrolled in FORWARD I had low FRα levels that should have precluded enrollment; and
- the protocol-defined FRα high subset contained patients with a mixture of FRα expression levels



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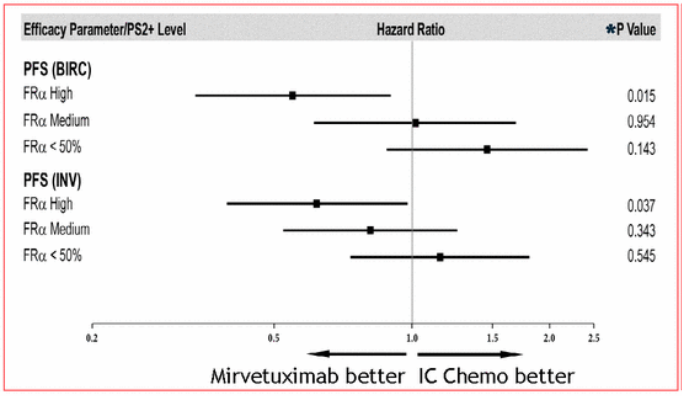
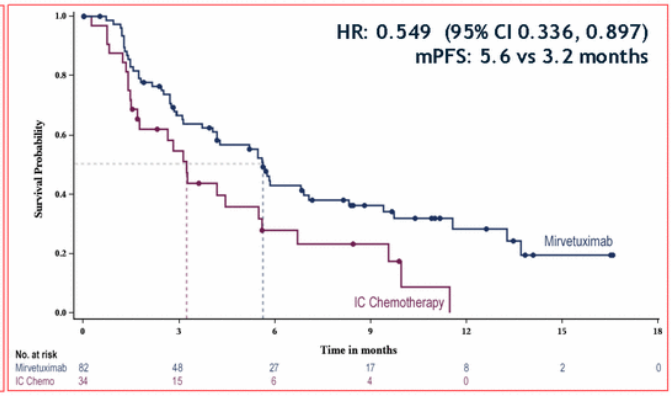
PS2+ Rescore: PFS Outcomes and Trends Across Subgroups

STRONG TREATMENT EFFECT IN INTENDED FRα HIGH POPULATION

PFS HAZARD RATIO PLOT



PFS (by BIRC) FRα HIGH



17 *Nominal p values
P values from unstratified log-rank test

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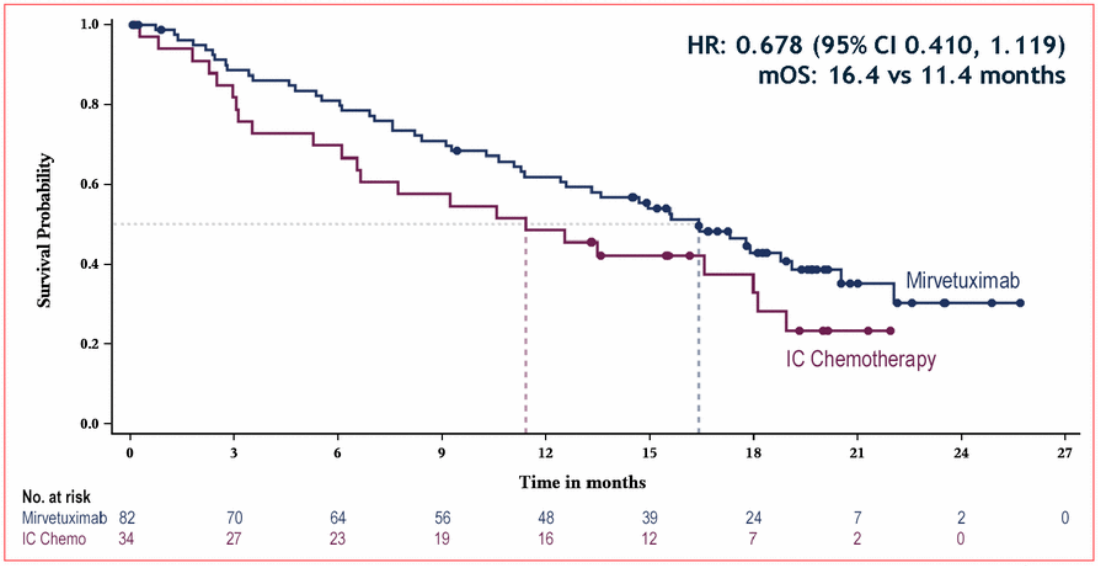
PS2+ Rescore: Overall Survival in FRα High (n=116)



(August 2019)

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PS2+ Rescore: Trends Across Subgroups

IMPROVED EFFICACY OUTCOMES CORRELATED WITH FRα EXPRESSION
STRONGEST TREATMENT EFFECTS FOR ALL EFFICACY ENDPOINTS IN THE FRα HIGH PATIENT POPULATION (BY PS2+ SCORING)

Endpoint	FRα < 50% (n=114) (Mirv vs IC Chemo)	FRα Medium (n=103) (Mirv vs IC Chemo)	FRα High (n=116) (Mirv vs IC Chemo)
PFS by BIRC (mo.)	HR: 1.458 (0.878, 2.420) mPFS: 3.8 vs 5.5	HR: 1.015 (0.611, 1.687) mPFS: 4.3 vs 5.6	**HR: 0.549** (0.336, 0.897) **mPFS: 5.6 vs 3.2**
ORR by BIRC 95% CIs	16% vs 16% (8%, 26%) vs (6%, 31%)	28% vs 18% (18%, 40%) vs (7%, 35%)	**29% vs 6%** (20%, 40%) vs (1%, 20%)
OS (*August 2019*) (mo.)	HR: 0.923 (0.548, 1.554) mOS: 14.0 vs 13.4	HR: 0.936 (0.542, 1.616) mOS: 15.9 vs 20.7	**HR: 0.678** (0.410, 1.119) **mOS: 16.4 vs 11.4**
PFS by INV (mo.)	HR: 1.149 (0.732, 1.803) mPFS: 4.0 vs 4.5	HR: 0.810 (0.523, 1.254) mPFS: 5.1 vs 2.8	**HR: 0.619** (0.394, 0.975) **mPFS: 5.6 vs 3.7**
ORR by INV 95% CIs	18% vs 21% (11%, 29%) vs (10%, 37%)	36% vs 24% (25%, 49%) vs (11%, 41%)	**38% vs 9%** (27%, 49%) vs (2%, 24%)

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FORWARD I Conclusions

- FORWARD I did not meet the PFS primary endpoint in the ITT or FRα high populations
- In the FRα high population (by 10X scoring), consistent efficacy signals were observed with mirvetuximab soravtansine
- Mirvetuximab soravtansine was well tolerated with a differentiated safety profile, fewer grade 3+ adverse events, fewer drug-related dose reductions/discontinuations, and more patients with improved abdominal/GI symptoms compared to chemotherapy
- Exploratory analyses suggest that the change in scoring method from PS2+ to 10X introduced a population of patients into FORWARD I with lower levels of FRα expression than intended
- Mirvetuximab soravtansine demonstrates improved outcomes correlated with FRα expression, with the strongest treatment effects for all efficacy endpoints in the FRα high patient population (by PS2+ scoring)
- MIRASOL, the next Phase 3 trial, in PS2+ FRα high patients is planned to begin by the end of 2019

MIRASOL Study Design: Phase 3 Registration Trial for Mirvetuximab Soravtansine Using PS2+ Scoring in FRα High Patients

MIRASOL

Enrollment and Key Eligibility

- 430 patients/330 events for PFS by INV
- Platinum resistant disease (<6 months PFI)
- Prior Bev and PARP allowed
- BRCAmut patients allowed

Statistical Assumptions

- α=0.05 (two-sided), Power = 90%, HR=0.7; control arm mPFS 3.5 mo

Mirvetuximab Soravtansine

6 mg/kg (adjusted ideal body weight) once every 3 weeks

1:1 Randomization

STRATIFICATION FACTORS
IC Chemotherapy Choice
(Paclitaxel, PLD, Topotecan)
Prior therapies
(1 vs 2 vs 3)

Investigator's Choice Chemotherapy
Paclitaxel, PLD†, or Topotecan

Paclitaxel: 80 mg/m² weekly
PLD: 40 mg/m² once every 4 weeks
Topotecan: 4 mg/m² on Days 1, 8, and 15 every 4 weeks; or 1.25 mg/m² on Days 1-5 every 3 weeks

Primary Endpoint

Progression-free survival by INV
BICR for sensitivity analysis*

Secondary Endpoints

Overall response rate by INV
Overall survival
Patient reported outcomes

*BICR: Blinded Independent Central Review
†PLD: pegylated liposomal doxorubicin

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Closing Remarks

Mark Enyedy
President and CEO

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Summary

FORWARD I

- Trial did not meet primary endpoint of progression-free survival
- Consistent efficacy signal seen in folate receptor alpha (FRα) high patients
- Favorable tolerability profile confirmed

Exploratory Analyses

- Change in scoring method from PS2+ to 10X introduced a population of patients into FORWARD I with lower levels of FRα expression than intended
- Analyses of patients scored using PS2+ demonstrate improved outcomes correlated with FRα expression
- Strongest treatment effect for all efficacy endpoints observed in FRα high population

Registration Study

- Data from FORWARD I inform patient selection and significantly improve the likelihood of a positive outcome
- New Phase 3 trial in FRα high patients expected to begin by the end of 2019

MIRASOL

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Q&A