ImmunoGen Announces Top-Line Results from Phase 3 FORWARD I Study of Mirvetuximab Soravtansine in Ovarian Cancer

March 1, 2019

Trial Did Not Meet Primary Endpoint of Progression-Free Survival

Efficacy Signal Seen in High Folate Receptor Alpha Patients; Additional Analyses to be Conducted

Favorable Tolerability Profile Confirmed

Combination Regimens to be Evaluated as an Independent Path Forward to Support Registration in Ovarian Cancer

Conference Call to be Held at 8 a.m. ET

WALTHAM, Mass.--(BUSINESS WIRE)--Mar. 1, 2019-- ImmunoGen, Inc., (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that its Phase 3 FORWARD I trial evaluating the safety and efficacy of mirvetuximab soravtansine compared to chemotherapy in patients with folate receptor alpha (FRα)-positive, platinum-resistant ovarian cancer did not meet its primary endpoint of progression-free survival (PFS) in either the entire study population or in the pre-specified subset of patients with high FRα expression.

“Even though FORWARD I did not meet its primary endpoint, I continue to be impressed with the efficacy and tolerability of mirvetuximab soravtansine in ovarian cancer patients, especially in the subset with high FRα expression,” said Dr. Kathleen Moore, Associate Director of Clinical Research at the Stephenson Cancer Center at the University of Oklahoma. “I look forward to continuing to work with ImmunoGen to analyze the Phase 3 data and determine the most appropriate path to bringing mirvetuximab soravtansine to those patients who benefit most from it.”

The FORWARD I Phase 3 trial randomized 366 patients 2:1 to receive either mirvetuximab soravtansine 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 have been treated with up to three prior regimens. The primary endpoint of this study was 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.

“Based upon the efficacy signals we observed in the high FRα subset with PFS, confirmed overall response rate and overall survival, we are conducting additional analyses to further evaluate the potential benefit of mirvetuximab soravtansine for FRα-positive platinum-resistant ovarian cancer,” said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. “We want to thank the patients who participated in this trial, the clinical investigators, and the support staff for their hard work, as we continue to pursue our goal of finding innovative cancer treatments for patients in need.”

Key findings from FORWARD I are as follows:

- In the entire study population, the confirmed overall response rate was higher for mirvetuximab soravtansine than for chemotherapy (22% vs 12%, p-value 0.015), without a significant difference in the primary endpoint of PFS (HR 0.98, p-value 0.897) or overall survival (HR 0.81, p-value 0.248).
- In the pre-specified high FRα subgroup (218/366, 60%)
    - PFS was longer in patients who received mirvetuximab soravtansine compared with chemotherapy (HR 0.69, 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 overall response rate was higher for mirvetuximab soravtansine than for chemotherapy (24% vs 10%, p-value 0.014).
    - Overall survival was longer in patients who received mirvetuximab soravtansine compared with chemotherapy (HR 0.62, p-value 0.033).
- Mirvetuximab soravtansine was well-tolerated, with fewer patients experiencing grade 3 or greater adverse events (46% vs 61%), fewer dose reductions (20% vs 31%), and fewer discontinuations due to drug-related adverse events (5% vs 8%) compared with chemotherapy.
- The safety profile of mirvetuximab soravtansine was confirmed, with the most common adverse events including nausea (54% all grades; 2% grade 3 or greater), diarrhea (44% all grades; 4% grade 3 or greater), and blurred vision (43% all grades; 3% grade 3 or greater).

“This study with mirvetuximab did not result in the outcome that we had hoped for in platinum-resistant patients. We will further assess the data from FORWARD I to determine potential next steps with a monotherapy approach. In parallel, we have generated encouraging data with mirvetuximab combination regimens and will evaluate our ongoing studies as an independent path forward to support a registration in ovarian cancer,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “ImmunoGen is in a strong financial position with approximately $295 million in cash on our balance sheet, and we will continue to advance our portfolio of next-generation ADCs, which includes three additional development candidates

targeting a range of tumor types in both hematologic malignancies and solid tumors.”

ImmunoGen intends to present additional results from FORWARD I at an upcoming medical meeting.

CONFERENCE CALL INFORMATION
ImmunoGen will host a conference call on March 1, 2019 at 8 a.m. ET to discuss the top-line findings from the FORWARD I trial. To access the live call by phone, dial 334-323-0522; the conference ID is 7188781. The call may also be accessed through the "Investors and Media" section of the Company's website, www.immunogen.com. Following the live webcast, a replay of the call will be available at the same location through March 15.

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 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. This trial was intended to support full marketing approval of mirvetuximab soravtansine for patients with platinum-resistant ovarian cancer.

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 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.” The Company has built a productive platform generating a broad pipeline of ADCs targeting solid tumors and hematologic malignancies.

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 based on management's current expectations. These statements include, but are not limited to, ImmunoGen’s plan to further assess the data from FORWARD I, ImmunoGen’s expectations with respect to the future development of mirvetuximab soravtansine as a monotherapy or in combination regimens, ImmunoGen’s plan to advance its portfolio of next-generation ADCs, ImmunoGen's ability to expand the addressable patient population for mirvetuximab soravtansine and the regulatory and commercial potential of mirvetuximab combinations in earlier lines of therapy. 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. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including risks related to preclinical and clinical studies, their timings and results, and the potential that earlier clinical studies may not be predictive of future results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2017 and other reports filed with the Securities and Exchange Commission.

View source version on businesswire.com: https://www.businesswire.com/news/home/20190301005092/en/

Source: ImmunoGen, Inc.

INVESTOR RELATIONS CONTACT
Sarah Kiely
781-895-0600
sarah.kiely@immunogen.com

MEDIA CONTACT
Courtney O’Konek
781-895-0600
courtney.okonek@immunogen.com

OR

FTI Consulting
Robert Stanislaro
212-850-5657
robert.stanislaro@fticonsulting.com