January 26, 2017

ImmunoGen Announces First Patient Dosed in FORWARD I Phase 3 Study of Mirvetuximab Soravtansine in Platinum-Resistant Ovarian Cancer

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that the first patient has been dosed in FORWARD I, the Company's Phase 3 clinical trial evaluating mirvetuximab soravtansine as a single-agent therapy for the treatment of platinum-resistant ovarian cancer. Mirvetuximab soravtansine is a first-in-class, folate receptor alpha (FRα)-targeting ADC.

"Dosing the first patient in our Phase 3 FORWARD I study marks an important milestone in our efforts to deliver mirvetuximab soravtansine to patients in need and to drive innovation in the field of ADCs. Mirvetuximab soravtansine has the potential to meaningfully improve the lives of patients with platinum-resistant ovarian cancer, and our top priority is advancing this program as quickly as possible," said Anna Berkenblit, M.D., Vice President and Chief Medical Officer of ImmunoGen.

"Given the prognosis for most patients with platinum-resistant ovarian cancer is poor and the benefit of approved agents is modest, we need better therapies that offer improved outcomes in terms of efficacy and tolerability," said Kathleen Moore, M.D., FORWARD I Co-Principal Investigator, and Associate Professor, Stephenson Cancer Center, University of Oklahoma. "We are excited about the potential of mirvetuximab soravtansine and are looking forward to evaluating this promising agent in a pivotal study."

FORWARD I is a Phase 3 trial in which 333 patients will be 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 will have been diagnosed with platinum-resistant ovarian cancer that expresses medium or high levels of FRα and will have been treated with up to three prior regimens. The primary endpoint of this study is progression free survival (PFS), which will be 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 is partnering with the GOG Foundation Inc., a leader in clinical research in gynecologic malignancies, on FORWARD I, which is being conducted in North America and Europe. This trial is 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 FRα-targeting ADC. It uses a 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.

Mirvetuximab soravtansine is ImmunoGen's lead program and is now in Phase 3 testing as a single agent for the treatment of platinum-resistant ovarian cancer. The candidate is also being assessed in combination regimens for both platinum-resistant and platinum-sensitive disease in Phase 1b/2 FORWARD II trial.

About Ovarian Cancer and FRα
It is estimated that 23,000 women are diagnosed annually with ovarian cancer in the US. With more than 14,000 deaths each year, ovarian cancer accounts for more deaths than any other cancer of the female reproductive system.[1]

Standard first-line therapy for ovarian cancer is a platinum-based regimen. Once the cancer becomes platinum-resistant, treatment options include single-agent cytotoxic therapies such as pegylated liposomal doxorubicin, paclitaxel, or topotecan, and combination therapies that include Avastin®.

There is a significant need for more effective, better-tolerated therapies for recurrent ovarian cancer. It is estimated that 19,000-24,000 women have platinum-resistant ovarian cancer requiring second-line or later treatment.[2] ImmunoGen estimates that 60% of ovarian cancer cases have medium or high FRα expression.

About ImmunoGen
ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary ADC technology. ImmunoGen's lead product candidate, mirvetuximab soravtansine, is in a Phase 3 trial for FRα-positive platinum-resistant ovarian cancer, and is in Phase 1b/2 testing in combination regimens for earlier-stage disease.

ImmunoGen's ADC technology is used in Roche's marketed product, Kadcyla®, in three other clinical-stage ImmunoGen product candidates, and in programs in development by partners Amgen, Bayer, Biotest, CytomX, Lilly, Novartis, Sanofi and Takeda. More information about the Company can be found at www.immunogen.com.

Kadcyla® and Avastin® are registered trademarks of Genentech, a member of the Roche Group.

[1]American Cancer Society, Cancer Facts & Figures 2016

[2]Decision Resources Group Patientbase

This press release includes forward-looking statements. 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. It should be noted that there are risks and uncertainties related to the development of novel anticancer products, including mirvetuximab soravtansine, including risks related to preclinical and clinical studies, their timings and results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended June 30, 2016 and other reports filed with the Securities and Exchange Commission.

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Source: ImmunoGen, Inc.