ImmunoGen Announces FDA Fast Track Designation for Mirvetuximab Soravtansine in Patients with Platinum-Resistant Ovarian Cancer

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WALTHAM, Mass.--(BUSINESS WIRE)--Jun. 18, 2018-- ImmunoGen, Inc. (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its lead program, mirvetuximab soravtansine. The designation is for the treatment of patients with medium to high folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer who received at least one, but no more than three prior systemic treatment regimens, and for whom single-agent chemotherapy is appropriate as the next line of therapy.

“We are pleased the FDA has granted Fast Track designation for mirvetuximab soravtansine,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “Patients with platinum-resistant ovarian cancer have a poor prognosis and we are encouraged by the FDA's recognition of the significant need for new therapeutic options that may be addressed by mirvetuximab as monotherapy. This important designation is based on the promising safety and activity findings observed to-date and we look forward to working closely with the FDA as we advance the development of mirvetuximab.”

The FDA’s Fast Track Designation is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously.

Mirvetuximab soravtansine is being evaluated in the FORWARD I Phase 3 trial. The trial is designed to randomize 333 patients 2:1 to receive either mirvetuximab soravtansine or the physician's choice of single-agent chemotherapy. Eligibility criteria include patients with platinum-resistant ovarian cancer that express medium or high levels of FRα who have been treated with up to three prior regimens. The primary endpoint of this study is Progression Free Survival, which is being assessed in the entire study population and in the subset of patients with high FRα expression. Enrollment of FORWARD I was completed ahead of schedule in April 2018 and ImmunoGen expects to report top-line results from the FORWARD I trial in the first half of 2019.

ImmunoGen is partnering with the Gynecologic Oncology Group 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 for patients with platinum-resistant ovarian cancer.

Mirvetuximab soravtansine is also being assessed in multiple combinations in the FORWARD II trial. FORWARD II is a Phase 1b/2 study of mirvetuximab in combination with Avastin® (bevacizumab), or Keytruda® (pembrolizumab) in patients with FRα-positive platinum-resistant ovarian cancer, primary peritoneal, or fallopian tube tumors, as well as a triplet combination of mirvetuximab plus carboplatin and Avastin in patients with platinum-sensitive 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 Ovarian Cancer and FRα

It is estimated that 22,000 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 combination 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 approximately 19,000 women in the US and approximately 24,000 women in the EU 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 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.” Our lead product candidate, mirvetuximab soravtansine, is in Phase 3 study for folate receptor alpha (FRα)-positive platinum resistant ovarian cancer, and in Phase 1b/2 testing in combination regimens. Our novel IGN candidates for hematologic malignancies, IMGN779 and IMGN632, are in Phase 1 studies. Learn more about who we are, what we do, and how we do it at www.immunogen.com.

Keytruda® and Avastin® are registered trademarks of their respective owners.

[1] American Cancer Society. Cancer Facts & Figures 2018. Atlanta, Ga: American Cancer Society; 2018.

[2] Decision Resources Group Patientbase.

This press release includes forward-looking statements based on management's current expectations. These statements include, but are not limited

to, 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.

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