March 12, 2017

ImmunoGen Presents Phase 1 Biopsy Expansion Cohort Data at the Society of Gynecologic Oncology Annual Meeting

Data Confirm Use of Archival Tumor Tissue to Determine Patient Selection in FORWARD I

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 data from a mirvetuximab soravtansine (IMGN853) Phase 1 biopsy expansion cohort demonstrate that archival tumor tissue can reliably identify patients with folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer. These data will be presented at the Society of Gynecologic Oncology (SGO) Annual Meeting, which is being held March 12-15 in National Harbor, MD.

"In the Phase 3 FORWARD I registration trial for mirvetuximab soravtansine, FRα expression for patient selection is being assessed based on archival tumor tissue samples," said Anna Berkenblit, M.D., Vice President and Chief Medical Officer of ImmunoGen. "The results being presented at SGO support this strategy to select patients for our Phase 3 FORWARD I trial. More broadly, the data being presented confirm that in this heavily pretreated cohort, mirvetuximab soravtansine is well tolerated and that the higher the FRα expression, the greater the anti-tumor activity."

The objectives of the biopsy expansion cohort were to:

- Characterize FRα expression in archival tumor tissue and in pre- and post-treatment biopsy samples obtained from a heterogeneous population of relapsed epithelial ovarian cancer (EOC) patients;
- Determine the concordance rate between archival tissue and pre-treatment biopsy FRα expression levels; and
- Compare changes in FRα expression levels before and after treatment with mirvetuximab soravtansine in biopsy samples.

In the biopsy expansion cohort, a total of 27 heavily pretreated patients (including patients with up to 11 prior therapies) were enrolled based on FRα expression levels in archival tumor tissue. Patients underwent a pre-treatment biopsy prior to receiving mirvetuximab soravtansine and a post-treatment biopsy after two doses of mirvetuximab soravtansine.

A comparison of FRα levels in pre-treatment biopsies versus archival samples supports the use of archival tumor tissue for patient selection. Of the 21 evaluable pre-treatment samples, 15 met the eligibility criterion for the biopsy expansion cohort (≥ 25% cells with ≥ 2+ intensity), resulting in a 71% concordance with archival tumor tissues. Twenty-two percent (22%) of patients (6/27) did not have pre-treatment biopsies evaluable for FRα immunohistochemistry due to insufficient tumor cells present in the specimens. Additionally, biopsies taken prior to and following two doses of mirvetuximab soravtansine showed similar FRα expression levels. The findings also support the use of a pre-treatment biopsy for patient selection if archival tumor tissue is not available for evaluation.

The safety profile of the cohort was consistent with that previously reported for mirvetuximab soravtansine-treated EOC patients across the Phase 1 study, with predominately Grade 1 and 2 adverse events. Based on FRα expression in both archival and pre-treatment biopsies, the data also demonstrated that anti-tumor activity increased with higher FRα expression levels.

Presentation

Title: "Characterization of folate receptor alpha (FRα) expression in archival tumor and biopsy samples in a phase I study of mirvetuximab soravtansine, a FRα-targeting antibody-drug conjugate (ADC), in relapsed epithelial ovarian cancer patients" (abstract #61)

The findings will be presented during featured poster presentation discussion sessions:

- Monday, March 13, 3:30-5:00pm ET
- Tuesday, March 14, 3:30-4:30pm ET

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

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 in Phase 3 testing (the FORWARD I trial) 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 FORWARD I

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 Ovarian Cancer and FRα

It is estimated that 22,500 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, Inc.

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® is a registered trademark of Genentech, a member of the Roche Group.

[1]American Cancer Society, Cancer Facts & Figures 2017

[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, and risks related to clinical studies, their timing and results. A review of these risks can be found in ImmunoGen's transition report on Form 10-K for the six-month transition period ended December 31, 2016 and other reports filed with the Securities and Exchange Commission.

Investor Contact
ImmunoGen, Inc.
Sarah Kiely, 781-895-0600
sarah.kiely@immunogen.com
or
Media Contact
FTI Consulting, Inc.
Robert Stanislaro, 212-850-5657
robert.stanislaro@fticonsulting.com

Source: ImmunoGen, Inc.