June 1, 2014

ImmunoGen, Inc. Announces Favorable STARLYTE Phase II Clinical Data with Sanofi's SAR3419 in Diffuse Large B-Cell Lymphoma

- *SAR3419 achieved objective responses well above the study threshold and was found to have a favorable safety profile.*
- *Objective responses reported in patients whose disease had not responded to prior therapy.*
- *Selected for Best of ASCO.*

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (NASDAQ: IMGN), a biotechnology company that develops novel anticancer therapeutics using its antibody-drug conjugate (ADC) technology, today announced the presentation of favorable clinical findings with SAR3419 (coltuximab ravtansine) from the STARLYTE Phase II trial in diffuse large B-cell lymphoma (DLBCL). SAR3419 is a CD19-targeting ADC developed by ImmunoGen and licensed to Sanofi as part of a broader collaboration between the companies. The study results were reported in an oral abstract session at the American Society of Clinical Oncology (ASCO) 50th Annual Meeting being held in Chicago, IL; they were also selected for Best of ASCO (abstract #8506).

In the data presented today, study investigators reported achievement of proof of concept, with 43.9% objective response rate (ORR) for the per protocol population (patients with relapsed or relapsed/refractory disease). The primary objective of the study was to assess whether single agent SAR3419 could achieve an ORR of at least 20% in this patient population using Cheson 2007 criteria. Additionally, objective responses were reported among the patients enrolled with primary refractory disease - cancer that had not responded to first-line treatment - with a 21.4% ORR.

"SAR3419 demonstrated promising activity against previously treated DLBCL, including disease that had not responded to first-line treatment," commented Daniel Junius, president and CEO of ImmunoGen. "We believe the unique profile of SAR3419 can make an important difference for patients with DLBCL, and potentially for other types of B-cell malignancies. These data also add to the growing body of favorable findings with ADCs using our technology."

The STARLYTE trial is evaluating the efficacy and safety of SAR3419 used as a single agent to treat relapsed or relapsed/refractory CD19-positive DLBCL. Patients received SAR3419 at 55 mg/m^2 weekly for four weeks and then every other week until disease progression or discontinuation. Of the patients enrolled in the trial, 55 were evaluable for efficacy and 61 were evaluable for safety.

The 41 per protocol patients included 26 patients with relapsed but not refractory disease and 15 patients with disease refractory to their last treatment. Among these patients:

- The ORR was 53.8% among the patients with relapsed disease, with 69.2% having stable disease or better. The 14 patients with objective responses included 5 patients with complete responses (CRs) and 9 patients with partial responses (PRs).
- Among the 15 patients with disease refractory to the last treatment, the ORR was 26.7%, with 46.7% having stable disease or better. These included 1 CR and 3 PRs.

The 55 efficacy evaluable patients also included 14 individuals with primary refractory disease. Among these patients, the ORR was 21.4%, with 35.7% having stable disease or better. The objective responses reported included 1 CR as well as 2 PRs.

The investigators reported that SAR3419 was found to have a favorable safety profile, with few treatment-related grade 3/4 adverse events (AEs) or serious AEs reported. No grade 3 or 4 peripheral neuropathy or ocular events were observed; any ocular events were low grade (1 or 2), manageable and reversible. Moderate hematological toxicities were reported including anemia, thrombocytopenia and neutropenia.

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics. The Company's ADC technology uses tumor-targeting antibodies to deliver an ImmunoGen cell-killing agent specifically to cancer cells; the Company has also developed antibodies with anticancer activity of their own. The first product with ImmunoGen's ADC technology is Roche's Kadcyla®. ImmunoGen has three wholly owned product candidates in clinical testing with additional compounds in clinical testing through the Company's partnerships with Amgen, Bayer HealthCare, Biotest and Sanofi. More information about ImmunoGen can be found at www.immunogen.com.

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

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 SAR3419, 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, 2013 and other reports filed with the Securities and Exchange Commission.

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