September 6, 2012

ImmunoGen, Inc. Announces Presentation of New IMGN901 Clinical Data

- Phase I evaluation presented established IMGN901 dose being used in Phase II assessment — the NORTH trial — for first-line treatment of small-cell lung cancer (SCLC).
- IMGN901 able to be administered at full single-agent dose in combination regimen assessed.
- Encouraging activity reported in treatment of SCLC.

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (Nasdaq: IMGN), a biopharmaceutical company that develops anticancer therapeutics using its antibody expertise and Targeted Antibody Payload (TAP) technology, today announced the presentation of clinical data for the Company's IMGN901 targeted anticancer compound at the Chicago Multidisciplinary Symposium in Thoracic Oncology.

"The data being reported today are from the dose-finding evaluation conducted to establish the recommended Phase II dose for our NORTH trial," commented James O'Leary, MD, Vice President and Chief Medical Officer. "IMGN901 was able to be administered in combination with a standard etoposide/carboplatin regimen at its full single-agent dose, which speaks to the favorable tolerability profile of this compound. Additionally, while enrollment wasn't limited to patients with SCLC, the findings seen in those patients are encouraging."

The Dose-Finding Evaluation Conducted

This Phase I assessment was designed to establish the dose of IMGN901 to be used in combination with etoposide (E) and carboplatin (C) in a Phase II assessment — the NORTH trial — of this combination regimen for the first-line treatment of SCLC. E/C is a standard treatment for newly diagnosed, extensive disease SCLC, and the NORTH trial is designed to assess whether adding IMGN901 to E/C provides a meaningful additional clinical benefit. In this assessment, IMGN901 is administered on Days 1 and 8 every 21 days.

Enrollment in the dose-finding evaluation was open to patients with any type of advanced solid tumors appropriately treated with E/C. All patients received E at its standard dose of 100 mg/m^2, given on Days 1-3 every 21 days. Two different doses of C are widely used with E — C AUC5 and C AUC6 — and thus escalating doses of IMGN901 were evaluated with each. C is administered on Day 1 every 21 days. A total of 33 patients received one of the five dose combinations assessed (two alternative IMGN901 doses with C AUC6 and three with C AUC5). Thirteen of these patients had SCLC.

Phase II Dose Established

The Phase II dose established was IMGN901 at 112 mg/m^2 with C AUC5 and E at 100 mg/m^2. Higher IMGN901 doses were not evaluated as 112 mg/m^2 was the maximum tolerated dose established in an assessment of IMGN901 given as a single agent in another trial with the D1, D8 every 21 days dosing schedule.

The overall safety profile of IMGN901 used with C/E was consistent with that of IMGN901 and of C/E used separately. Low grade (1 or 2) peripheral neuropathy was the most common adverse event considered by the investigators to be related to the treatment regimen, as reported previously for IMGN901, while myelosuppressive events were the most common related grade 3 or 4 events, as reported previously for C/E.

Activity Noted

Three of the 13 patients with SCLC enrolled had chemotherapy-naïve disease. Two of these three patients had an objective response (partial response or PR) by RECIST criteria to treatment with IMGN901 plus E/C.

All of the 10 patients with previously treated SCLC had received prior platinum-based therapy, and seven of these patients had platinum-resistant/refractory disease. Four of these ten patients had a PR, including two of the patients with platinum-resistant/refractory disease.

Among all of the 33 patients enrolled, ten had an objective response, and 24 (72.7%) had disease control (objective response or stable disease).

ImmunoGen's NORTH Trial

The 120-patient NORTH trial is designed to evaluate the efficacy and safety of IMGN901 for first-line treatment of extensive disease SCLC. All patients enrolled are provided with up to six cycles of C/E. Two-thirds of the patients enrolled are randomized to also receive IMGN901. These patients can elect to remain on IMGN901, as monotherapy, after completion of the C/E cycles if benefiting from treatment. The trial is designed to compare the findings in the IMGN901-including treatment arm to historic controls, with the control arm serving to verify consistency with historical results.

The NORTH trial utilizes a Simon Two-Stage Design: once 59 patients have been enrolled across the two study arms, those two cohorts of patients will be followed for an interim analysis of progression-free survival (PFS) at 6 months. The interim analysis will focus on whether the IMGN901-including treatment arm met pre-defined clinical benefit hurdles. Success on this interim analysis will serve as a basis for certain development decisions by the Company.

The primary endpoint of the NORTH trial is PFS. Secondary endpoints include PFS at 6 months, overall survival at 12 months, time to progression, overall survival, and overall response rate.

About IMGN901

IMGN901 is designed to target and kill CD56+ cancer cells. This TAP compound is wholly owned by ImmunoGen and consists of the Company's CD56-targeting antibody with its DM1 cancer-cell killing agent attached using one of its engineered linkers. IMGN901 has been granted orphan drug designation for SCLC in the US and Europe.

In addition to SCLC, other CD56+ cancers include multiple myeloma and Merkel cell carcinoma. In early-stage clinical testing, IMGN901 has demonstrated encouraging activity in these cancers as well as in SCLC and also has orphan drug designation for them.

About SCLC

It is estimated that approximately 29,400 new cases of SCLC will be diagnosed in the United States this year.[1] SCLC almost universally expresses CD56. Approximately two-thirds of patients have extensive disease at the time of diagnosis, as SCLC tends to spread broadly through the body quite early in its course.[2] As a result, SCLC is usually treated with chemotherapy rather than with surgery.[3] Median PFS for extensive disease SCLC is approximately 5.5 months, while median overall survival averages 9-11 months.[3,4]

About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics using the Company's expertise in tumor biology, monoclonal antibodies, potent cancer-cell killing agents and engineered linkers. The Company's TAP technology uses monoclonal antibodies to deliver one of ImmunoGen's proprietary cancer-killing agents specifically to tumor cells. There are now ten TAP compounds in clinical development, of which three are wholly owned by the Company. ImmunoGen's collaborative partners include Amgen, Bayer HealthCare, Biotest, Lilly, Novartis, Roche, and Sanofi. A marketing application for trastuzumab emtansine (T-DM1), the most advanced compound using ImmunoGen's TAP technology, has been submitted in the US. Roche is developing this compound under an agreement between ImmunoGen and Genentech, a member of the Roche Group. More information about ImmunoGen can be found at www.immunogen.com.

[1] American Cancer Society, Cancer Facts & Figures 2012.

[2] American Cancer Society, Lung Cancer (Small Cell) 2012.

[3] Socinski, MA, Smith, EF, Lorigan, P, et al. (2009). J Clin Oncol, 27(28).

[4] Foster, NR, Qi, Y, Krook, JE, et al. (2009). J Clin Oncol, 27(15s).

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 IMGN901, including risks related to 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, 2012 and other reports filed with the Securities and Exchange Commission.

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