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ImmunoGen, Inc. Attains Patient Enrollment Milestone in IMGN901 NORTH Trial

WALTHAM, Mass.--(BUSINESS WIRE)-- [ImmunoGen, Inc.](#) (NASDAQ: IMGN), a biotechnology company that develops targeted anticancer therapeutics, today announced that it has completed patient enrollment in the first stage of its NORTH two-stage Phase II trial. The NORTH trial is assessing the Company's IMGN901 product candidate for first-line treatment of extensive disease small-cell lung cancer (SCLC). Attaining this milestone enables the findings from the planned interim analysis of PFS at 6 months to be available in 2H2013.

The NORTH trial is designed to assess whether IMGN901 provides a clinically meaningful benefit when used in conjunction with a standard-of-care for this cancer, etoposide plus carboplatin (E/C). Patients with newly diagnosed extensive disease SCLC enrolled in the trial are randomized, two-to-one, to treatment either with IMGN901 plus E/C or with E/C alone.

While the NORTH trial is designed to include a total of 120 patients, its two-stage design specifies that an analysis of PFS at six months is to be performed with the first 39 evaluable patients randomized to the IMGN901 plus E/C treatment arm. Patient enrollment of this cohort of patients — and the corresponding 20 patients in the E/C alone arm — has now been completed. These patients will now be followed for the interim analysis while patient enrollment continues.

"Achieving timely enrollment of patients with small-cell lung cancer is known to be challenging, and we believe our attainment of this milestone on schedule speaks to both the clinical need for new therapies for SCLC and our increasing strength as a development company," commented James O'Leary, MD, Vice President and Chief Medical Officer. "When available, we intend to use the findings from the interim analysis to make decisions related to the development of IMGN901. We also plan to submit them for presentation at a medical conference."

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 E/C, standard-of-care for this cancer. 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 E/C cycles if benefiting from treatment.

The primary endpoint of the NORTH trial is progression-free survival (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 was developed by ImmunoGen to target and kill CD56-positive cancer cells. CD56 is expressed on virtually all cases of SCLC. It is also expressed on a variety of other cancers including Merkel cell carcinoma and many cases of multiple myeloma.

IMGN901 employs the Company's Targeted Antibody Payload (TAP) technology, which uses a CD56-binding antibody to target one of ImmunoGen's highly potent cell-killing agents to CD56-positive cancer cells.

About SCLC

It is estimated that approximately 29,400 new cases of SCLC will be diagnosed in the United States this year.¹ 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. The Company's TAP technology uses a tumor-targeting monoclonal antibody to deliver one of ImmunoGen's highly potent cancer-killing agents specifically to tumor cells. Ten TAP compounds are now in clinical testing, of which three are wholly owned by the Company. Marketing applications for trastuzumab emtansine (T-DM1), the most advanced compound using ImmunoGen's TAP technology, are under review in the US, Europe and Japan. Roche is developing this compound globally 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 [National Comprehensive Cancer Network](#) (NCCN) Guidelines.

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 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, 2012 and other reports filed with the Securities and Exchange Commission.

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