

ImmunoGen, Inc. Announces Initiation of Phase II Evaluation of Its IMG901 Product Candidate

- NORTH trial assesses impact of adding IMG901 to standard care for first-line treatment of small-cell lung cancer (SCLC).
- Trial includes planned interim analysis to enable early decisions on next steps to advancement.

WALTHAM, Mass.--(BUSINESS WIRE)-- [ImmunoGen, Inc.](#) (Nasdaq: IMG9) today announced that it has initiated Phase II testing of its IMG901 product candidate for first-line treatment of SCLC.

The Phase II assessment begun today, also known as the NORTH trial, is designed to evaluate whether the addition of IMG901 to standard first-line care for SCLC meaningfully impacts duration of progression-free survival (PFS). With SCLC, the efficacy of first-line treatment is considered to be particularly important due to the low likelihood of obtaining a marked, sustained response with any subsequent treatment.

"Our experience with IMG901 to date — preclinical and clinical — supports Phase II evaluation of IMG901 for first-line use in SCLC," commented James O'Leary, MD, Vice President and Chief Medical Officer. "SCLC almost universally expresses the CD56 antigen targeted by IMG901, and there is a clear need for more effective treatments for this cancer. We have a number of clinical sites already open for patient enrollment, with many additional sites on track to open over the next month."

About the NORTH Trial

The NORTH trial is designed to evaluate the efficacy and safety of IMG901 for first-line treatment of extensive disease SCLC. All patients enrolled will be provided with standard care for newly diagnosed patients with this cancer — up to six cycles of carboplatin plus etoposide (C/E). Two-thirds of patients enrolled will be randomized to receive IMG901 in addition to C/E. These patients can elect to remain on IMG901, as monotherapy, after completion of the C/E cycles if benefiting from treatment.

The trial is designed to include 120 patients (80 in the IMG901 plus C/E arm and 40 in the C/E alone arm). It utilizes a Simon Two-Stage Design. Once the specified number of patients has been enrolled (39 in the IMG901 plus C/E arm; 20 in the C/E alone arm), these patient cohorts will be followed to establish whether the treatment arm that includes IMG901 met the pre-defined hurdle for success, which is based on PFS at 6 months compared to historic controls. Success on this interim analysis will serve as a basis for certain development decisions by the Company.

The primary endpoint of the trial is PFS. Secondary endpoints include PFS at 6 months, overall survival at 12 months, time to progression, overall survival, and overall response rate. The trial is designed to compare these findings to historic controls, with its control arm serving to verify consistency with historical results.

The NORTH trial is the Phase II portion of a Phase I/II trial. The Phase I portion, which has been completed, was designed to establish the dose of IMG901 to be used in this Phase II assessment. This dose information is expected to be reported at a medical conference in 2H2012.

About IMG901 (lorvotuzumab mertansine)

IMG901 is designed to target and kill CD56-expressing cancer cells. It is wholly owned by ImmunoGen and consists of the Company's CD56-targeting antibody with its proprietary DM1 cancer-cell killing agent attached using one of its engineered linkers. IMG901 has been granted orphan drug designation for SCLC in the US and in Europe.

In addition to SCLC, other CD56-expressing cancers include multiple myeloma and Merkel cell carcinoma. IMG901 has demonstrated encouraging initial activity in these cancers as well as in SCLC in early-stage clinical testing, and also has orphan drug designation for these cancers.

About Small-Cell Lung Cancer (SCLC)

It is estimated that approximately 31,000 new cases of SCLC were diagnosed in the US last year.^{1,2} SCLC tends to spread broadly through the body quite early in the course of the disease, and approximately two-thirds of SCLC patients have extensive disease at the time of diagnosis.² As a result, the disease is usually treated with chemotherapy rather than with

surgery.² 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 Targeted Antibody Payload (TAP) technology uses monoclonal antibodies to deliver one of ImmunoGen's proprietary cancer-cell killing agents specifically to tumor cells. There are now numerous TAP compounds in clinical development with a wealth of clinical data reported. ImmunoGen's collaborative partners include Amgen, Bayer HealthCare, Biotest, Lilly, Novartis, Roche, and Sanofi. The most advanced compound using ImmunoGen's TAP technology, trastuzumab emtansine (T-DM1), is in Phase III testing through the Company's collaboration with Genentech, a member of the Roche Group. More information about ImmunoGen can be found at www.immunogen.com.

¹ACS Cancer Facts & Figures 2011 (2012).

²ACS Lung Cancer (Small Cell) (2012).

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

⁴Foster, 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 IMG901, 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, 2011 and other reports filed with the Securities and Exchange Commission.

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