## May 14, 2014

# ImmunoGen, Inc. Announces Clinical Data Presentations at Upcoming 50th Annual Meeting of ASCO

- Abstracts made public today provide insight on biological effects seen at low doses with IMGN529 and on observed activity threshold for IMGN853.
- Abstracts also add to growing body of data on the significance of partner compounds, including the findings reported on the activity and tolerability of SAR3419 in the Phase II STARLYTE trial.

WALTHAM, Mass.--(BUSINESS WIRE)-- ImmunoGen, Inc. (NASDAQ: IMGN), a biotechnology company that develops novel anticancer therapeutics using its antibody-drug conjugate (ADC) technology, today provided information on the data presentations on Company and partner compounds to be made at the 2014 American Society of Clinical Oncology (ASCO) annual meeting, which will be held May 30-June 3 in Chicago, IL. New clinical data are being presented on ImmunoGen wholly owned compounds, IMGN529 and IMGN853, as well as on partner compounds SAR3419, SAR650984 and Kadcyla<sup>®</sup> (ado-trastuzumab emtansine).

"The presentations on our wholly owned product candidates reflect the unique and promising profile of these compounds as well as our strengthened drug development capabilities," commented Daniel Junius, President and CEO. "At the same time, the presentations on partner compounds add to the growing body of data on the importance of these compounds."

### IMGN529

<u>Poster presentation</u>: Friday, May 30, 1:00-4:00pm CT; Lymphoma and Plasma Cell Disorders Poster Highlights Session, S405, poster board #6. <u>Abstract #8526</u>: "Preliminary findings from a phase I, multicenter, open-label study of the anti-CD37 antibody-drug conjugate (ADC), IMGN529, in adult patients with relapsed or refractory non-Hodgkin lymphoma (NHL)."

IMGN529 contains a CD37-targeting antibody that demonstrates pronounced activity against CD37-positive cancer cells in preclinical models with the potent cytotoxic agent, DM1, attached. It is currently in dose-finding Phase I clinical testing for the treatment of NHL; its maximum-tolerated dose (MTD) is not yet established.

The data made public today in the abstract include that patient dosing with IMGN529 began at 0.1 mg/kg, administered once every three weeks, with new cohorts of patients receiving progressively higher dose levels up to 0.8 mg/kg. As the Company disclosed late last year, biological changes were unexpectedly observed at these low doses.

As reported in the abstract, these included the occurrence of Grade 3 or 4 asymptomatic neutropenia or febrile neutropenia in 5 and 2, respectively, of the 18 patients enrolled. The biological changes also included a post-dosing reduction in lymphocytes, consistent with IMGN529's anticancer mechanism of action. Additionally, 2 patients had partial remissions (PRs): a patient with follicular lymphoma treated at 0.2 mg/kg and a patient with diffuse large B-cell lymphoma treated at 0.4 mg/kg.

Many patients have been treated with ADCs containing DM1 to targets other than CD37 without evidence of activity at such low dose levels and without neutropenia. In researching the neutropenia reported, it was found that, in the majority of the patients, it occurred shortly after the patient received the first dose of IMGN529 and was transient in nature, suggesting it was a manifestation of cytokine release. The study protocol was thus amended to include peri-infusional steroids as a prophylactic method. The abstract made public today includes favorable initial findings after this protocol change.

#### **IMGN853**

Poster presentation: Saturday, May 31, 8:00-11:45am CT; Gynecologic Cancer Poster Session, S Hall A2, poster board #353. <u>Abstract #5571:</u> "Relationship of pharmacokinetics (PK), toxicity, and initial evidence of clinical activity with IMGN853, a folate receptor alpha (FRα)-targeting antibody drug conjugate in patients with epithelial ovarian cancer (EOC) and other FRα-positive solid tumors."

IMGN853 comprises a FRα-targeting antibody with the potent DM4 cytotoxic agent attached. This ADC is a potential treatment for FRα-positive solid tumors - which include many ovarian and endometrial cancers - and is currently in dose-finding Phase I clinical testing. As reported previously, dosing in the trial was changed from use of patient total body weight (TBW) to adjusted ideal body weight (AIBW) based on findings from PK modeling that AIBW should minimize inter-patient variability in IMGN853 blood levels.

The data in the abstract made public today are from 30 patients treated with IMGN853 before the change from TBW to AIBW. As noted, 24 of these patients were treated at doses of 3.3 mg/kg or more, administered once every three weeks. This compares with 13 patients in the findings reported at ASCO in 2013 because of the treatment of additional patients at the 3.3 and/or 5.0 mg/kg dose levels.

As disclosed in the abstract, preliminary evidence of clinical activity was observed in 10 of these 24 patients, with clinical activity defined as CA-125 response by CGIC criteria, stable disease lasting 18 or more weeks, and/or an objective response. It was observed that a quantifiable, minimum level of total exposure to IMGN853 was associated with evidence of anticancer activity. Clinical activity was seen in 5 of the 6 patients with ovarian cancer (serous or transitional EOC) and in 2 of the 4 patients with endometrial cancer whose IMGN853 exposure exceeded this level.

It was previously reported that the occurrence of its dose-limiting toxicity (DLT) was associated with IMGN853 blood levels

exceeding definable thresholds.<sup>1</sup> That IMGN853 activity is associated with total exposure while its DLT is associated with peak exposure supports achievement of an appropriate therapeutic window and that dosing IMGN853 in smaller amounts more frequently may be preferable to once every three week dosing. Assessment of a modified weekly schedule was added to the ongoing Phase I trial earlier this year.

# **Presentations on Partner Compounds**

In addition to multiple presentations on Kadcyla, data will be presented on the CD19-targeting ADC SAR3419 and the CD38targeting antibody SAR650984, which are in development by Sanofi through a collaboration with ImmunoGen. Among the data made public today are findings from the STARLYTE Phase II trial showing SAR3419 therapy achieved a 43.9% objective response rate (ORR) when used as a single agent to treat relapsed/refractory diffuse large B-cell lymphoma; an objective of the study was to determine if it could achieve an ORR of at least 20%. Only grade 1-2 eye disorders were reported, including one patient with unrelated grade 2 keratitis.

Abstract #8532 "A phase I trial of SAR650984, a CD38 monoclonal antibody, in relapsed or refractory multiple myeloma."

• Poster presentation: Friday, May 30, 1:00-4:00 CT, S 405, poster board #12

<u>Abstract #8506</u> "STARLYTE phase II study of coltuximab ravtansine (CoR, SAR3419) single agent: Clinical activity and safety in patients (pts) with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL; NCT01472887)."

• Oral abstract: Sunday, June 1, 10:12am-10:24am CT, E Hall D2

<u>Abstract #8512</u> "A phase Ib dose escalation trial of SAR650984 (Anti-CD-38 mAb) in combination with lenalidomide and dexamethasone in relapsed/refractory multiple myeloma."

• Oral abstract: Monday, June 2, 8:48-9am CT, E354a

Additional information - including full abstracts - can be found at <u>www.asco.org</u>.

# 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<sup>®</sup>. 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.

<sup>1</sup>Ponte et al., AACR 2014, abstract #4641.

Kadcyla<sup>®</sup> 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 IMGN529 and IMGN853, 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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