# ImmunoGen

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## ImmunoGen Announces Recent Product Program Advancements and Anticipated 2016 Events in Advance of J.P. Morgan Healthcare Conference

WALTHAM, Mass.--(BUSINESS WIRE)-- <u>ImmunoGen, Inc.</u> (Nasdaq: IMGN), a biotechnology company that develops targeted anticancer therapeutics using its antibody-drug conjugate (ADC) technology, today announced recent product program advancements and anticipated 2016 events in advance of the 34<sup>th</sup> Annual J.P. Morgan Healthcare Conference.

"ImmunoGen made significant progress in 2015 that is anticipated to lead to a number of meaningful events in 2016 and beyond," commented Å Daniel Junius, President and CEO. "For mirvetuximab soravtansine, our lead program, these include completing patient enrollment in three disease-specific cohorts that can provide informative data in 2016. They also include putting in place the FORWARD I trial intended to support an Accelerated Approval pathway as well as the FORWARD II combination trial. Additionally, we put in place a trial to assess our IMGN529 in combination with rituximab, established a development strategy for coltuximab ravtansine, and submitted an IND for IMGN779, the first ADC to utilize one of our new DNA-acting cancer-killing agents."

Mr. Junius continued, "Our partners, too, made important progress, with Roche reporting global growth in Kadcyla<sup>®</sup>sales, encouraging initial clinical findings reported with Bayer's anetumab ravtansine, Novartis, Lilly, Sanofi, and Amgen all advancing ADCs with ImmunoGen technology into the clinic, and a new collaboration established with Takeda. We expect several key partner events in 2016, including the advancement of two programs into trials designed to support product registration."

**Mirvetuximab soravtansine** - the first folate receptor  $\alpha$  (FR $\alpha$ )-targeting ADC.

2015 accomplishments include:

- Presentation of the first clinical data from assessment in a disease-specific patient population that demonstrated the potential of mirvetuximab soravtansine, used alone, to make a meaningful difference for patients with heavily pretreated FRα-positive ovarian cancer.
  - Activity was most notable among patients with high or medium amounts of FRα on their cancer cells, the majority of the patients.
- Completion of patient enrollment in three disease-specific Phase I cohorts (enrollment target):
  - Patients with platinum-resistant FRα-positive ovarian cancer (40 patients);
  - i Patients with platinum-resistant FRα-positive ovarian cancer consenting to the required biopsies (20 patients); and
  - i Patients with relapsed/refractory FRα-positive endometrial cancer (20 patients).
- Establishment of a development strategy that includes:
  - Assessment as single-agent therapy for patients with FRα-positive ovarian cancer treated with 3-4 prior regimens. This Phase 2 trial, FORWARD I, is intended to support an Accelerated Approval pathway.

In December, ImmunoGen and the GOG Foundation, Inc. entered into a partnership designed to help patients with ovarian cancer learn about FORWARD I and, if appropriate, enroll in the study. Patient dosing in trial is poised to start.

- i Assessment for FRα-positive ovarian cancer in three doublet combinations with either pegylated liposomal doxorubicin (Doxil®), bevacizumab (Avastin®), or carboplatin; additional cohorts are possible. ImmunoGen is conducting this Phase 1b/2 trial, FORWARDÂ II, to potentially expand the number of patients able to benefit from mirvetuximab soravtansine. Patient dosing is underway.
- <sup>i</sup> Preclinical evaluation of additional types of cancers for potential clinical assessment.

Events anticipated in 2016 include:

 Meeting with regulators in 1H2016 on the mirvetuximab soravtansine development program, including the design of the second stage of the FORWARD I trial.

- Presentation of clinical data from the 40-patient ovarian cancer cohort at a medical meeting in 2Q2016.
- Presentation of clinical data from additional expansion cohorts.
- Advancing FORWARD I and FORWARD II. ImmunoGen plans to ultimately have more than 50 centers open in the US, Canada, and Western Europe for FORWARD I patient enrollment.

**IMGN529** - CD37-targeting ADC for diffuse-large B-cell lymphoma (DLBCL) and potentially other non-Hodgkin lymphoma (NHL) subtypes.

#### 2015 accomplishments include:

- Completion of dosing-finding Phase 1 evaluation of IMGN529 used as monotherapy. IMGN529 demonstrated encouraging single-agent activity in patients with heavily pretreated NHL, particularly ones with DLBCL.
- Establishment of strategy to evaluate IMGN529 in combination with rituximab (Rituxan®) in a Phase 2 trial based on distinctive synergy seen in preclinical models.
- Design and start of implementation of this Phase 2 trial, with patient dosing expected to start shortly.

#### Anticipated in 2016:

- Advancing Phase 2 combination trial.
- Potentially other program updates.

Coltuximab ravtansine - CD19-targeting ADC for DLBCL and potentially other NHL subtypes.

#### 2015 accomplishments include:

- Regaining coltuximab ravtansine rights from Sanofi.
- Establishment of strategy to advance in a combination regimen.
- Preclinical evaluation of alternatives for selection of regimen to be assessed clinically.

#### Events anticipated in 2016 include:

- Disclosure of combination regimen to be assessed in 1H2016.
- Initiation of Phase 2 combination study midyear.

**IMGN779** - Novel CD33-targeting ADC for acute myeloid leukemia (AML) and potentially other malignancies. IMGN779 is the first ADC utilizing one of ImmunoGen's new DNA-acting IGNs as the cancer-killing agent.

#### 2015 accomplishments include:

IND submitted and active, ImmunoGen's fourth IND in four years.

#### Events anticipated in 2016 include:

Initiation of Phase 1 testing for the treatment of AML in 1H2016.

Partner Programs - ImmunoGen has a distinctive record of successful partnerships.

There are now ten novel anticancer compounds, including Kadcyla®, in the clinic for a broad range of solid and liquid cancers through ImmunoGen partnerships with Amgen, Bayer, Biotest, Lilly, Novartis, Roche and Sanofi.

### 2015 accomplishments include:

- Amgen, Lilly, Novartis and Sanofi each advanced a novel ADC with ImmunoGen technology into clinical testing.
- Study investigators presented encouraging Phase 1 clinical findings with Bayer's anetumab ravtansine in pretreated mesothelioma.

- A collaboration was established with Takeda in early 2015, and in December, Takeda took its first license for the exclusive right to develop ADCs to an undisclosed target using ImmunoGen technology. The taking of this license triggers ImmunoGen recognition of approximately \$8.6 million of (non-cash) revenue in its quarter ending December 31, 2015.
- In December, CytomX announced it is advancing a novel anticancer agent targeting CD166 using its Probody<sup>TM</sup> technology and ImmunoGen's ADC technology under a strategic collaboration established between the companies in early 2014. This event does not impact ImmunoGen financial results.

#### Events anticipated in 2016 include:

- Two partner compounds begin testing in trials designed to support product registration.
- At least one additional partner compound disclosed and/or advances into clinical testing.

#### **Cash Position**

ImmunoGen will report the financial results for the quarter ended December 31, 2015 on January 29, 2016. The Company noted that it ended the quarter with approximately \$212 million in cash and cash equivalents and had no debt.

#### About ImmunoGen, Inc.

ImmunoGen is a clinical-stage biotechnology company that develops targeted anticancer therapeutics with its proprietary ADC technology. The Company's lead product candidate, mirvetuximab soravtansine, is a potential treatment for folate receptor α-positive ovarian cancers and other solid tumors. A number of major healthcare companies have licensed limited rights to use ImmunoGen's ADC technology to develop novel anticancer therapies; it is used in Roche's marketed product, Kadcyla<sup>®</sup>. More information about the Company can be found at <u>www.immunogen.com</u>.

Doxil<sup>®</sup>, Avastin<sup>®</sup>, Rituxan<sup>®</sup> and Kadcyla<sup>®</sup> are registered trademarks of their respective owners.

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 risks related to clinical studies, regulatory reviews, and product commercialization, 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, 2015 and other reports filed with the Securities and Exchange Commission.

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