# ImmunoGen, Inc. Reports Second Quarter Fiscal Year 2014 Financial Results and Provides Corporate Update

-Quarterly Conference Call Today at 8:00 am ET-

- Progress with all three wholly owned ImmunoGen compounds in clinical testing IMGN853, IMGN529, IMGN289; decision
  made to discontinue IMGN901 development.
- Marked increase in partner activity in latter part of 2013, with multiple data presentations and development events expected in 2014.
- Company expects to use less cash in 2014 fiscal year than previously projected; updates guidance.

WALTHAM, Mass.--(BUSINESS WIRE)-- <u>ImmunoGen, Inc.</u> (Nasdaq: IMGN), a biotechnology company that develops novel anticancer therapeutics using its antibody-drug conjugate (ADC) technology, today reported financial results for the three-month period ended December 31, 2013 - the second quarter of the Company's 2014 fiscal year. ImmunoGen also provided an update on Company and partner product programs.

"We expect 2014 to be a very active year," commented Daniel Junius, President and CEO. "We are implementing a data-driven strategy to ensure we have the optimal dosing of IMGN853 for later testing and are planning several data presentations in 2014. We are making solid progress with our IMGN529 compound and expect to report the first clinical data mid-year. While our EGFR-targeting ADC, IMGN289, just entered the clinic in November, we believe there is the potential for data presentation and/or development decisions in the back half of this year. And we continue to expand our opportunity to create anticancer products that make a meaningful difference for patients, as evidenced by our recent presentations on our new platform of payload agents and our latest novel linker as well as by our collaboration with CytomX for access to their novel Probody™ technology. "

Mr. Junius continued, "This is expected to be an important year for Kadcyla® - in terms of patients, sales development, and the expected reporting of results from the MARIANNE trial. At the same time, seven other highly promising partner compounds also are advancing. We expect a considerable amount of data to be reported in 2014 and next-step decisions to be made for several partner compounds."

## **Pipeline Update**

Eleven compounds are now in the clinic through ImmunoGen product programs and those of its partners.

- All compounds with ImmunoGen technology that have entered the clinic since the Kadcyla IND continue to advance.
- ImmunoGen expects one or more additional partner compounds to advance into clinical testing in 2014.

Kadcyla (ado-trastuzumab emtansine) - The first marketed product with ImmunoGen's ADC technology, Kadcyla is being developed and commercialized by Roche under an agreement with the Company.

- Earlier this week, Roche reported 2013 Kadcyla sales of 222 million CHF in the US and 12 million CHF ex-US (in total, approximately \$250 million). Kadcyla was approved and launched in the US in February 2013 and in some international markets over the course of 2013. ImmunoGen receives and recognizes royalties on Kadcyla sales in the quarter after the quarter in which Roche records the sales.
- In November 2013, Kadcyla was approved for marketing in the European Union, the second largest pharmaceutical
  market globally. As with other international markets, the timing of launches in individual EU countries will vary depending
  on reimbursement processes.
- Roche has opened the Phase III trial, KAITLIN, to assess Kadcyla for adjuvant use in patients with operable HER2-positive breast cancer. Roche reported in October that it also plans to assess Kadcyla for neoadjuvant use for this cancer and expects to have pathological complete response (pCR) results in late 2015. Roche continues to expect to have results from its MARIANNE trial in late 2014 and from its GATSBY trial in early 2015, and, with positive outcomes, to apply in 2015 for first-line treatment of HER2-positive metastatic breast cancer and second-line treatment of advanced HER2-positive gastric cancer, respectively, with the findings from these trials.

cancers, including many ovarian, endometrial and lung cancers.

- The Company plans to present the data in support of dosing IMGN853 based on adjusted ideal body weight (AIBW) at a scientific conference in 2Q 2014. ImmunoGen also intends to report patient data at a medical conference in mid-2014 showing the impact of AIBW dosing on therapeutic window.
- ImmunoGen expects to begin enrolling patients with platinum-resistant ovarian cancer and those with relapsed/refractory endometrial cancer in 1H 2014 in the first IMGN853 Phase I expansion cohorts and to report the first disease-specific data with the compound in 2H 2014. These patients will receive IMGN853 using the current dosing schedule.
- ImmunoGen will also evaluate IMGN853 administered with a more frequent dosing regimen, to enable the best dosing regimen to be used in further evaluation of the compound.

IMGN529 - This novel ADC is a potential new treatment for CD37-positive B-cell malignancies, including non-Hodgkin lymphoma (NHL), and is wholly owned by ImmunoGen.

- ImmunoGen expects the first IMGN529 clinical data to be reported at a medical conference in mid-2014.
- The Company expects patient dosing in expansion phase cohorts to begin in 2H 2014.

IMGN289 - This EGFR-targeting ADC is a potential new treatment for many lung, head and neck cancers, including EGFR-positive tumors resistant to EGFR inhibition. It is wholly owned by ImmunoGen.

• The Company advanced IMGN289 into the clinic in November 2013. The Company potentially could report initial clinical findings and/or development steps in 2H 2014.

BT-062 - This CD138-targeting ADC is in development by Biotest. ImmunoGen has an opt-in right for its co-development and co-commercialization jointly with Biotest in the US.

- Initial findings with BT-062 used in combination with Revlimid® (lenalidomide) plus dexamethasone ("len/dex") to treat heavily pretreated multiple myeloma (MM) were reported in an oral presentation at ASH in December 2013. The findings included that the combination was well tolerated at the selected dose and that 100% of evaluable patients had a response to treatment of stable disease or better, including all of the len/dex-refractory patients. The expansion part of this Phase I trial is ongoing.
- Patient enrollment is expected to start in early 2014 in a Biotest trial assessing BT-062 for the treatment of bladder cancer and triple-negative breast cancer.

SAR650984 - This CD38-targeting therapeutic antibody was developed by ImmunoGen and licensed to Sanofi as part of a research collaboration between the companies.

Its first clinical data were reported at ASH in December and selected for "Best of ASH." When used as a single agent to
treat heavily pretreated MM, 77% of evaluable patients had a response to SAR650984 of stable disease or better. Its
maximum tolerated dose was not yet established.

SAR3419 - This CD19-targeting ADC also was developed by ImmunoGen and licensed to Sanofi as part of the research collaboration.

- Phase II data reported at ASH showed SAR3419 was well tolerated and demonstrated activity, even among patients with primary refractory disease, when used in combination with Rituxan® (rituximab) to treat diffuse large B-cell lymphoma previously treated with several lines of standard therapies, including Rituxan. Two other SAR3419 Phase II trials are ongoing in relapsed/refractory DLBCL and in acute lymphoblastic leukemia.
- This follows presentation of encouraging initial clinical findings with another ADC from the collaboration, SAR566658, at AACR-NCI-EORTC in October, as previously reported.

Clinical testing of Bayer's BAY 94-9343 and Amgen's AMG 172 and AMG 595 is ongoing, with potential for data disclosures and/or development-related events in 2014.

## **Financial Results**

For the Company's quarter ended December 31, 2013 (2Q FY2014), ImmunoGen reported net income of \$3.8 million, or \$0.04 per basic and diluted share, compared to a net loss of \$24.4 million, or (\$0.29) per basic and diluted share, for the same quarter last year (2Q FY2013).

Revenues for 2Q FY2014 were \$30.1 million, compared to \$2.6 million for 2Q FY2013. Revenues in the current period include \$25.7 million of license and milestone fees, compared to \$0.4 million in 2Q FY2013. The FY2014 fees include \$18.2 million of amortization of fees from Novartis that were recognized in 2Q FY2014 principally due to Novartis taking two development and commercialization licenses in the quarter. The Novartis fees amortized include upfront fees received from Novartis in FY2011 with the establishment of the multi-target agreement and in 2Q FY2014 with their execution of a one-year extension to that agreement. Additionally, the 2Q FY2014 revenues include a \$5.0 million milestone payment from Roche earned with the approval of Kadcyla in the EU and \$2.2 million of amortization of upfront license fees from Amgen. Revenues in 2Q FY2014 also include \$2.3 million of royalty payments received from Roche in December 2013 for sales of Kadcyla during the three-month period ended September 30, 2013 and \$1.9 million of research and development support fees, compared to \$2.0 million in such fees for 2Q FY2013.

Operating expenses in 2Q FY2014 were \$26.3 million, compared to \$27.1 million in 2Q FY2013. Operating expenses in 2Q FY2014 include research and development expenses of \$20.9 million, compared to \$21.7 million in 2Q FY2013. This change is primarily due to less cost for third-party production of antibody for use in our own clinical materials, decreased clinical trial costs driven by the discontinuation of the IMGN901 trial and increased capitalization to inventory of costs to manufacture clinical materials on behalf of our partners, partially offset by increased personnel expenses. The difference in reimbursement of costs to manufacture clinical materials is due to the variable nature of the number of batches of clinical materials produced for partners on a quarter-to-quarter basis. Operating expenses also include general and administrative expenses of \$5.4 million in 2Q FY2014, compared to \$5.5 million in 2Q FY2013.

ImmunoGen had approximately \$178.1 million in cash and cash equivalents as of December 31, 2013, compared with \$195.0 million as of June 30, 2013, and had no debt outstanding in either period. Cash used in operations was \$21.6 million in the first six months of FY2014, compared with \$42.7 million in the same period in FY2013. Capital expenditures were \$2.3 million and \$2.0 million for the first six months of FY2014 and FY2013, respectively.

## **Updated Financial Guidance for Fiscal Year 2014**

ImmunoGen is updating its financial guidance for FY2014 from that issued in October 2013. ImmunoGen now expects:

- Revenues to be between \$71 million and \$75 million, unchanged from previous guidance;
- Operating expenses to be between \$140 million and \$144 million, unchanged from previous guidance;
- Net loss to be between \$67 million and \$71 million, unchanged from previous guidance;
- Net cash used in operations to be between \$64 million and \$68 million, reduced from the \$69 million to \$73 million range in the previous guidance;
- Capital expenditures to be between \$8 million and \$10 million, unchanged from previous guidance; and
- To end its fiscal year on June 30, 2014 with cash and cash equivalents of between \$124 million and \$128 million, increased from the \$119 million to \$123 million range in the previous guidance.

The changes in projected cash used in operations and ending cash and cash equivalents principally reflect the reductions in cash expenses now anticipated for the year, offset by the non-cash expenses expected to be recorded with the establishment of the collaboration with CytomX entered into earlier this month. The accounting treatment of that transaction, however, is still under review.

"These financial results reflect our business model of developing anticancer products to make a meaningful difference for patients and using partnerships as an important - and growing - source of non-dilutive capital," commented David B. Johnston, EVP and CFO.

#### **Conference Call Information**

ImmunoGen is holding a conference call today at 8:00 am ET to discuss the quarterly results. To access the live call by phone, dial 913-312-0388; the passcode is 8088204. The call also may be accessed through the Investor Information section of the Company's website, <a href="https://www.immunogen.com">www.immunogen.com</a>. Following the live webcast, a replay of the call will be available at the same location through February 14, 2014.

## About ImmunoGen, Inc.

ImmunoGen, Inc. develops targeted anticancer therapeutics. The Company's ADC technology uses a tumor-targeting engineered antibody to deliver one of ImmunoGen's highly potent cancer-cell killing agents specifically to tumor cells; the Company has also developed antibodies with anticancer activity of their own. The most advanced compound with ImmunoGen's ADC technology is Roche's Kadcyla, which is marketed in the US by Genentech and is also gaining approvals internationally.

Additional compounds are in clinical testing by ImmunoGen and through the Company's partnerships with Amgen, Bayer HealthCare, Biotest and Sanofi. More information about ImmunoGen can be found at <a href="https://www.immunogen.com">www.immunogen.com</a>.

 $Kadcyla^{\$}$ ,  $Revlimid^{\$}$ , and  $Rituxan^{\$}$  are registered trademarks of their respective owners. Probody<sup>TM</sup> is a trademark GytomX Therapeutics, Inc.

This press release includes forward-looking statements based on management's current expectations. These statements include, but are not limited to, ImmunoGen's expectations related to: the Company's revenues, operating expenses, net loss, cash used in operations and capital expenditures in its 2014 fiscal year; its cash and marketable securities as of June 30, 2014; the occurrence, timing and outcome of potential pre-clinical, clinical and regulatory events related to the Company's and its collaboration partners' product programs; and the presentation of preclinical and clinical data on the Company's and collaboration partners' product candidates. 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. Various factors could cause ImmunoGen's actual results to differ materially from those discussed or implied in the forward-looking statements, and you are cautioned not to place undue reliance on these forward-looking statements, which are current only as of the date of this release. Factors that could cause future results to differ materially from such expectations include, but are not limited to: the timing and outcome of ImmunoGen's and the Company's collaboration partners' research and clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense and results of preclinical studies, clinical trials and regulatory processes; ImmunoGen's ability to financially support its product programs; ImmunoGen's dependence on collaborative partners; and other factors more fully described 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.

-Financials Follow-

### IMMUNOGEN, INC.

**SELECTED FINANCIAL INFORMATION** (in thousands, except per share amounts)

## **CONDENSED CONSOLIDATED BALANCE SHEETS** (Unaudited)

	Dec	ember 31, 2013	June 30, 2013
ASSETS			
Cash and cash equivalents Other assets	\$	178,088 24,435	\$ 194,960 18,636
Total assets	\$	202,523	\$ 213,596
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities  Long-term portion of deferred revenue and other long-term	\$	17,633	\$ 19,173
liabilities		54,854	72,576
Shareholders' equity		130,036	121,847
Total liabilities and shareholders' equity	\$	202,523	\$ 213,596

## **CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS** (Unaudited)

Three Months Ended			Six Months Ended			
December 31,		December 31,				
	2013	2012	2013	2012		

License and milestone fees Royalty revenue	\$ 25,678 2,335	\$ 429	\$ 38,845\$ 4,388	1,362
Research and development support Clinical materials revenue	1,922 125	2,036 147	3,912 133	3,413 1,928
Total revenues	 30,060	2,612	47,278	6,703
Expenses:				
Research and development	20,862	21,656	42,891	45,356
General and administrative	 5,447	5,464	11,973	11,103
Total operating expenses	26,309	27,120	54,864	56,459
Income (loss) from operations	3,751	(24,508)	(7,586)	(49,756)
Other income, net	 62	115	172	171
Net income (loss)	\$ 3,813	\$(24,393)	<u>\$ (7,414)</u> <u>\$</u>	(49,585)
Net income (loss) per common share, basic and diluted	\$ 0.04	<b>\$</b> (0.29)	<u>\$ (0.09)</u> \$	(0.59)
Weighted average common shares outstanding, diluted	 87,276	84,147	85,221	83,748

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