# ImmunoGen, Inc. Reports Third Quarter Fiscal Year 2011 Financial Results and Provides Quarterly Update

Trastuzumab emtansine (T-DM1) submission for 1st-line use expected a year earlier than previously projected due to accelerated pace of patient enrollment. Significant progress achieved with proprietary pipeline, with two new compounds advancing toward IND filing within 12 months.

WALTHAM, Mass., Apr 28, 2011 (BUSINESS WIRE) --

ImmunoGen, Inc. (Nasdaq: IMGN), a biotechnology company that develops targeted antibody-based anticancer products using its antibody expertise and Targeted Antibody Payload (TAP) technology, today reported financial results for the three-month period ended March 31, 2011 - the third quarter of the Company's 2011 fiscal year (3Q FY2011).

"Our recent achievements underscore our focus on enhancing our development capabilities while maintaining our research strength," said Daniel Junius, President and CEO. "We're making solid progress evaluating our IMGN901 compound as part of combination regimens - interim findings from the multiple myeloma trial were accepted for oral presentation at ASCO in June, and we're on schedule to begin the randomized phase of our small-cell lung cancer trial later this year. We're now assessing our IMGN388 product candidate using a weekly dosing schedule and expect to report initial findings later this year. We presented highly encouraging data on our IMGN529 and IMGN853 preclinical compounds at AACR in April, with both on track for IND filing within the next twelve months."

Mr. Junius continued, "Roche's progress with T-DM1, now called trastuzumab emtansine, continues to generate excitement, and we look forward to seeing mature data this fall from the Phase II trial evaluating it for first-line treatment of HER2+ metastatic breast cancer. We're particularly pleased that Roche now expects to submit for this indication in 2014 - a year earlier than previous projections - using their MARIANNE Phase III trial. We expect other product candidates in development through our partnerships to start gaining prominence this year as well as a marked increase in the number of clinical-stage partner compounds."

#### **Clinical-Stage Product Candidates**

Trastuzumab emtansine (formerly T-DM1, trastuzumab-DM1) - In global development by Roche for treatment of HER2+ breast cancer (BC) under a collaboration agreement with ImmunoGen.

- 2nd-line use Roche reported that, as of Dec. 31, 2010, over 550 patients at 216 sites in 22 countries had been
  enrolled in the EMILIA Phase III trial assessing trastuzumab emtansine for 2nd-line treatment of advanced HER2+ BC.
  Roche expects to apply in 2012 for marketing approval for this use in the US and Europe.
- 1st-line use Roche reported earlier this month that, in a randomized Phase II trial, patients receiving trastuzumab emtansine first line for HER2+ metastatic BC had a significant improvement in progression-free survival compared with those receiving Herceptin<sup>®</sup> (trastuzumab) plus chemotherapy. The data are expected to be reported at a medical conference later this year.

Roche also recently disclosed that it now plans to apply in 2014 rather than in 2015 for approval of trastuzumab emtansine for first-line use in HER2+ metastatic BC.

- Adjuvant/neoadjuvant use A Phase II trial is underway assessing the safety of trastuzumab emtansine in this setting.
- Gastric cancer In preclinical research reported at AACR, trastuzumab emtansine was found to be more active than
  trastuzumab against gastric cancer. Its activity was even greater when trastuzumab emtansine was used in combination
  with pertuzumab.

IMGN901 (lorvotuzumab mertansine) - ImmunoGen product candidate for CD56+ cancers.

- Small-cell lung cancer (SCLC) Solid progress is being made in the Phase I, dose-finding portion of the Phase I/II trial, and enrollment in the Phase II portion remains on track to begin in 2H 2011. The first data from this trial are expected to be reported at a medical conference in 4Q 2011.
- Merkel cell carcinoma The Company is preparing to initiate a pivotal trial for this use in mid-to-late 2012, with the final decision to be informed by early findings in the SCLC trial and regulatory discussions.
- Multiple myeloma Interim findings will be reported in an oral presentation at ASCO from the early-stage clinical trial
  assessing IMGN901 used in combination with lenalidomide/ dexamethasone for this disease. The trial evaluating
  IMGN901 as a single agent for this cancer has been completed.

IMGN901 has orphan drug status for these three cancers in the US and Europe.

SAR3419 - ImmunoGen-created CD19-targeting compound in development by sanofi-aventis for non-Hodgkin's lymphoma.

- Clinical data from an early-stage trial assessing SAR3419 dosed weekly will be presented at two major medical conferences in June: ASCO and the International Conference on Malignant Lymphoma.
- This compound is on track to begin Phase II testing in 2H 2011. The Phase II program is designed to support rapid progression of the compound into pivotal testing.

IMGN388 - ImmunoGen product candidate for solid tumors.

- IMGN388 is now being assessed using weekly dosing in an early-stage clinical trial.
- The first findings with the weekly dosing schedule are expected to be reported at a medical conference in 4Q 2011.

SAR650984 and SAR566658 continue to progress through the Company's collaboration with sanofi-aventis, while BT-062 is advancing through ImmunoGen's collaboration with Biotest.

#### **Preclinical Product Candidates**

The Company expects six more TAP compounds to advance into clinical testing within the next 12-15 months - IMGN529 and IMGN853, which are wholly owned by ImmunoGen, and four other compounds through partnerships.

IMGN529 - ImmunoGen product candidate for B-cell malignancies, including non-Hodgkin's lymphoma (NHL) and chronic lymphocytic leukemia (CLL).

- The Company presented exciting preclinical data at AACR on the profile of this CD37-targeting TAP compound. Among the data reported were that CD37 expression is comparable to that of CD20 on key NHL subtypes and CLL; that in preclinical testing the antibody component of IMGN529 demonstrates anticancer activity comparable to or greater than that of Rituxan<sup>®</sup> (rituximab); and that the complete IMGN529 TAP compound antibody with attached DM1 cell-killing agent demonstrates significantly greater anticancer activity than rituximab in preclinical models.
- IND submission is on track for mid-2011.

IMGN853 - ImmunoGen compound for cancers that over-express folate receptor 1 (FOLR1).

- The Company also presented exciting preclinical data at AACR on this compound, including that IMGN853 uses a new linker developed by ImmunoGen scientists to combat cancer multi-drug resistance.
- IND submission is on track for early 2012.

"We're now averaging one new product candidate per year - up from earlier projections of one every 18 months - using our highly productive TAP technology together with our antibody expertise," said Gregory Perry, Executive Vice President and CFO. "Progress by our existing partners and the establishment of new collaborations provide us with meaningful non-dilutive financing, as reflected in the financial results we're reporting."

#### **Financial Results**

ImmunoGen reported a net loss of \$15.0 million, or \$0.22 per basic and diluted share, for the quarter ending March 31, 2011 (3Q FY2011), as compared to a net loss of \$12.1 million, or \$0.21 per basic and diluted share, for the same quarter of the last fiscal year (3Q FY2010).

Revenues were \$5.2 million for 3Q FY2011, as compared to \$3.3 million for the same period last year. Revenues in 3Q FY2011 include \$2.2 million of research and development support fees and \$2.2 million of clinical material reimbursement, compared to \$1.8 million and \$0.2 million, respectively, for the same quarter last year. Revenues in 3Q FY2011 also include \$0.9 million of license and milestone fees, compared to \$1.3 million for 3Q FY2010.

Operating expenses for 3Q FY2011 were \$20.3 million, compared to \$15.5 million in the same period last year. Operating expenses in 3Q FY2011 include research and development expenses of \$15.8 million, compared to \$12.1 million in 3Q FY2010. The increase in the current period is primarily due to greater investment being made in the Company's development of its proprietary product candidates, including costs associated with the enrollment of more patients in clinical trials and the advancement of IMGN529 and IMGN853 toward IND filing, as well as to increased cost of clinical materials reimbursed related to increased manufacturing on behalf of our partners. The operating expenses also include general and administrative expenses of \$4.6 million in 3Q FY2011, compared to \$3.4 million in 3Q FY2010. This increase is primarily due to increased patent and personnel costs.

ImmunoGen had approximately \$115.8 million in cash and marketable securities as of March 31, 2011, compared with \$110.3 million as of June 30, 2010, and had no debt outstanding in either period. Cash provided by operations was \$5.9 million in the first nine months of the Company's 2011 fiscal year, compared with \$30.9 million of cash used in operations during the same period in fiscal 2010. This \$36.8 million difference is driven principally by the \$45 million upfront payment received from Novartis in 2Q FY2011 with the establishment of a technology access collaboration between the companies. Capital expenditures were \$1.5 million and \$1.1 million for the first nine months of fiscal years 2011 and 2010, respectively.

#### **Financial Guidance**

ImmunoGen expects its net loss for its fiscal year ending June 30, 2011 to be between \$60-64 million, its cash used in operations to be between \$0-4 million, and its capital expenditures to be between \$2-3 million - all unchanged from previous guidance. Cash and marketable securities at June 30, 2011 are anticipated to be between \$106-110 million, also unchanged from previous guidance.

#### 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 TAP technology uses monoclonal antibodies to deliver one of ImmunoGen's proprietary cancer-cell killing agents specifically to tumor cells. There are currently six TAP compounds in the clinic, with a wealth of clinical data reported with the technology. ImmunoGen's collaborative partners include Amgen, Bayer HealthCare Pharmaceuticals, Biotest, Genentech (a member of the Roche Group), Novartis, and sanofiaventis. The most advanced compound using ImmunoGen's TAP technology, trastuzumab emtansine (formerly T-DM1), is in Phase III testing through the Company's collaboration with Genentech. More information about ImmunoGen can be found at <a href="https://www.immunogen.com">www.immunogen.com</a>.

Herceptin® in a registered trademark of Genentech, a member of the Roche Group.

Rituxan® is a registered trademark of Biogen Idec.

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 net loss, cash used in operations and capital expenditures in its 2011 fiscal year; its cash and marketable securities as of June 30, 2011; 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; industry merger and acquisition activity; and other factors more fully described in ImmunoGen's Annual Report on Form 10-K for the fiscal year ended June 30, 2010 and other reports filed with the Securities and Exchange Commission.

IMMUNOGEN, INC.
SELECTED FINANCIAL INFORMATION
(in thousands, except per share amounts)

## CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	March 31, 2011	June 30, 2010
ASSETS		
Cash, cash equivalents and marketable securities	\$ 115,813	\$ 110,298
Other assets	26,509	26,910

Total assets	\$ 142,322	\$	137,208
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities Long-term portion of deferred revenue and other long-term liabilities Shareholders' equity	\$ 13,370 64,129 64,823	-	13,822 21,338 102,048
Total liabilities and shareholders' equity	\$ 142,322	\$	137,208

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

	Three Mont March 31,	Three Months Ended March 31,		Nine Months Ended March 31,	
	2011	2010	2011	2010	
Revenues:					
Research and development support	\$ 2,190	\$ 1,805	\$ 5,690	\$ 3,870	
License and milestone fees	858	1,266	3,534	3,924	
Clinical materials reimbursement	2,163	243	3,576	1,727	
Total revenues	5,211	3,314	12,800	9,521	
Expenses:					
Research and development	15,763	12,091	45,192	36,490	
General and administrative	4,550	3,447	11,602	10,925	
Total operating expenses	20,313	15,538	56,794	47,415	
Loss from operations	(15,102)	(12,224)	(43,994)	(37,894)	
Other income (expense), net	99	(3)	1,870	122	
Loss before taxes	(15,003)	(12,227)	(42,124)	(37,772)	
(Benefit)/provision for income taxes	-	(103)	-	(265)	
Net loss	\$ (15,003)	\$ (12,124)	\$ (42,124)	\$ (37,507)	
Net loss per common share, basic and diluted	\$ (0.22)	\$ (0.21)	\$ (0.62)	\$ (0.66)	
Average common shares outstanding, basic and diluted	d 68,067	57,365	67,996	57,183	

SOURCE: ImmunoGen, Inc.

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