

August 4, 2016

## ImmunoGen Reports Fourth Quarter and Fiscal Year 2016 Financial Results and Provides Quarterly Business Update

- Conference call at 8:00 am ET today -

- Following positive meeting with FDA, Phase 3 FORWARD I study of mirvetuximab soravtansine in patients with platinum-resistant ovarian cancer on track to begin before year end.
- Mirvetuximab soravtansine plus Avastin<sup>®</sup> combination regimen advanced to Phase 2 in FORWARD II trial.
- Phase 1 testing of IMGN779 the first ADC deploying an ImmunoGen DNA-alkylating payload initiated in patients with acute myeloid leukemia (AML).
- Recent appointment of Mark Enyedy as President and CEO brings proven leadership and deep experience building oncology businesses.
- Company ended fiscal year with approximately \$245 million in cash and is moving to reporting on calendar-year basis.

WALTHAM, Mass.--(BUSINESS WIRE)-- <u>ImmunoGen, Inc.</u> (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today provided an update on the Company's progress and reported financial results for its fourth quarter and fiscal year ended June 30, 2016.

"With our lead candidate poised to enter Phase 3 and a portfolio of well-differentiated programs advancing behind it, I am excited to have joined the strong team managing ImmunoGen's transition to a fully-integrated biotech company," stated Mark Enyedy, President and CEO. "We will build upon ImmunoGen's leadership position in ADCs by focusing on four strategic priorities: complete development and commercialize mirvetuximab soravtansine, accelerate our earlier-stage portfolio, continue to drive innovation in ADCs for the treatment of cancer, and support new and existing partnerships. As we execute on these priorities, we will look to improve the efficiency of our operations and more effectively manage our cash position."

Mr. Enyedy continued, "We made significant progress on these priorities over the past three months, including meeting with the FDA to review the path to registration for mirvetuximab soravtansine and our proposed Phase 3 trial, FORWARD I. With the benefit of the guidance provided by the agency, we are moving ahead with the study as designed and expect to enroll our first patient before year end. Following successful dose escalation, we have also initiated a 35-patient, Phase 2 expansion cohort for mirvetuximab soravtansine in combination with Avastin as part of our FORWARD II trial. With the initiation of Phase 1 dose escalation for IMGN779 and the progression of IMGN632 into pre-IND testing, we continue to advance our earlier-stage candidates deploying our new IGN payload technology to broaden the range of ADC-treatable cancers. The progress with our product candidates and those of our partners demonstrates ImmunoGen's continuing commitment to drive ADC innovation to improve the lives of patients with cancer."

### **Pipeline Updates**

#### Mirvetuximab Soravtansine

Mirvetuximab soravtansine is a well-differentiated experimental therapy for the treatment of ovarian cancer and potentially other tumor types that express its target, folate receptor alpha (FRα). This ADC is being evaluated in clinical trials as a single-agent therapy for platinum-resistant ovarian cancer and in combination regimens for both platinum-resistant and platinum-sensitive disease.

### Single-Agent Therapy

- Held Type B meeting with the U.S. Food and Drug Administration (FDA) to review the path to registration for mirvetuximab soravtansine and the proposed FORWARD I study protocol. With the benefit of the agency's guidance, ImmunoGen is moving forward with initiating this Phase 3 trial as previously outlined, including with the primary endpoint of progression-free survival (PFS).
- Reported data from 46 patients with FRα-positive platinum-resistant ovarian cancer at the American Society of Clinical Oncology (ASCO) meeting in June. Mirvetuximab soravtansine demonstrated robust single-agent activity in

these patients, with the greatest response rates and PFS reported in patients with high or medium levels of FRα expression on their tumors and who had received up to three prior regimens, the patient population eligible for enrollment in FORWARD I.

#### Strategic Combination Regimens

- Initiated the 35-patient Phase 2 assessment in FORWARD II of mirvetuximab soravtansine in combination with Avastin following successful completion of dose finding.
- Continued enrollment in the FORWARD II cohorts assessing the ADC used with pegylated liposomal doxorubicin (PLD) and, separately, with carboplatin, with the cohort assessing the combination with Keytruda<sup>®</sup> on track to open this summer.

#### Exploring Additional Opportunities

Through ImmunoGen's collaboration with the National Comprehensive Cancer Network (NCCN), grants were awarded for clinical assessment of mirvetuximab soravtansine in combination with gemcitabine and as a treatment of triple negative breast cancer as well as for preclinical studies on mechanisms of resistance, sensitivity, and biomarkers.

#### IMGN779 / IMGN632

IMGN779 and IMGN632 deploy ImmunoGen's new ultra-potent, DNA-acting payload agents that alkylate DNA without crosslinking it. In preclinical studies, these agents have been found to avoid the sustained toxicity seen with DNA-crosslinking agents.

- Initiated Phase 1 clinical testing of IMGN779, a CD33-targeting ADC, for the treatment of AML. Initial clinical data from this trial are expected to be presented in 2017.
- Advanced CD123-targeting IMGN632 into IND-enabling testing. The first preclinical findings with this novel ADC were presented at the European Hematology Association annual meeting, with additional data on its distinctive activity and tolerability expected to be presented in late 2016.

#### IMGN529

IMGN529 deploys ImmunoGen's validated maytansinoid payload technology and recently gained orphan drug status in diffuse large B-cell lymphoma (DLBCL).

 Initiated Phase 2 clinical testing of IMGN529 used in combination with Rituxan<sup>®</sup> for patients with B-cell malignancies including DLBCL based on marked synergy in preclinical testing.

#### **Fiscal Year 2016 Financial Results**

ImmunoGen's fiscal year 2016 ended June 30, 2016. The Company is moving to reporting on a calendar year basis, effective January 1, 2017.

For the Company's fiscal year ended June 30, 2016 (FY2016), ImmunoGen reported a net loss of \$143.7 million, or \$1.65 per basic and diluted share, compared to a net loss of \$60.7 million, or \$0.71 per basic and diluted share, for its fiscal year ended June 30, 2015 (FY2015). For the quarter ending June 30, 2016, ImmunoGen reported a net loss of \$44.8 million, or \$0.51 per basic and diluted share, compared to a net loss of \$30.5 million, or \$0.35 per basic and diluted share, for the same quarter in FY2015.

Revenues in FY2016 were \$60.0 million, compared to \$85.5 million in FY2015, with the decrease principally due to reduced non-cash revenue from the amortization of upfront fees. FY2016 revenues include \$26.9 million of license and milestone fees compared to \$57.8 million in FY2015. The current period includes less revenue from the amortization of previously-received upfront fees than the prior period, \$8.6 million and \$41.4 million, respectively, and more revenue from partner milestone payments, \$18.0 million and \$14.0 million, respectively. Revenues in FY2016 also include \$25.5 million of royalty revenues, all but \$200,000 of which was non-cash, compared with \$19.4 million for FY2015, of which \$5.5 million was non-cash and \$13.9 million was cash. Revenues for FY2016 also include \$4.0 million of research and development support fees and \$3.6 million of clinical materials revenue, compared with \$2.8 million and \$5.5 million, respectively, in such fees for FY2015. The changes reflect variations in the level of research support and the number of batches of clinical materials produced and released to partners on a year-to-year basis.

Operating expenses in FY2016 were \$183.8 million, compared to \$140.0 million in FY2015, with the increase principally due to costs associated with ImmunoGen advancing mirvetuximab soravtansine and other innovative, wholly-owned product candidates. Research and development expenses were \$146.9 million in FY2016, compared to \$111.8 million in FY2015. The increase in FY2016 is primarily due to increased clinical trial costs, particularly related to mirvetuximab soravtansine, to greater third-party costs related to ImmunoGen product program advancement, and to increased personnel expenses, principally due to hiring in the first three quarters of FY2016. General and administrative expenses were \$36.9 million in FY2016, compared to \$28.2 million in FY2015. This increase is primarily due to increased personnel expenses, particularly higher non-cash stock compensation costs which include a substantial charge resulting from the CEO transition, and to a lesser extent, increased third-party service fees.

ImmunoGen had approximately \$245.0 million in cash and cash equivalents and \$100.0 million of convertible debt outstanding as of June 30, 2016, compared with \$278.1 million of cash and cash equivalents and no debt on June 30, 2015. Cash used in operations was \$124.5 million in FY2016, compared with \$55.3 million in FY2015. Capital expenditures were \$10.4 million and \$7.4 million for FY2016 and FY2015, respectively.

## **Financial Guidance**

ImmunoGen is transitioning to a fiscal year ending December 31, effective January 1, 2017. For the six months ending December 31, 2016, ImmunoGen expects: revenues to be between \$40 million and \$45 million; operating expenses to be between \$95 million and \$100 million; net loss to be between \$55 million and \$60 million; cash used in operations to be between \$65 million and \$70 million; and capital expenditures to be between \$2 million and \$5 million. Cash and marketable securities at December 31, 2016 are anticipated to be between \$170 million and \$175 million.

## **Conference Call Information**

ImmunoGen is holding a conference call today at 8:00 am ET to discuss these results. To access the live call by phone, dial 913-312-1463; the conference ID is 3243361. The call also may be accessed through the Investors section of the Company's website, <u>www.immunogen.com</u>. Following the live webcast, a replay of the call will be available at the same location through August 18, 2016.

## About ImmunoGen, Inc.

ImmunoGen is a clinical-stage biotechnology company that develops targeted cancer therapeutics using its proprietary ADC technology. ImmunoGen's lead product candidate, mirvetuximab soravtansine, is being advanced to a Phase 3 trial for FRα-positive platinum-resistant ovarian cancer, and is in Phase 1b/2 testing in combination regimens for earlier-stage disease. ImmunoGen's ADC technology is used in Roche's marketed product, Kadcyla<sup>®</sup>, in three other clinical-stage ImmunoGen product candidates, and in programs in development by partners Amgen, Bayer, Biotest, CytomX, Lilly, Novartis, Sanofi and Takeda.

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

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 for the six months ending December 31, 2016; its cash and marketable securities as of December 31, 2016; 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, 2015 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)

	June 30, 2016	June 30, 2015
ASSETS		
Cash and cash equivalents Other assets	\$245,026 <u>42,059</u>	\$278,109 35,714
Total assets	\$287,085	\$313,823
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities Long-term portion of deferred revenue and other long-term	\$ 60,277	\$ 35,810
liabilities	307,950	242,909
Shareholders' equity	(81,142)	35,104
Total liabilities and shareholders' equity	\$287,085	\$313,823

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(enadated)	Three Months Ended June 30,		Fiscal Year Ended June 30,	
	2016	2015	2016	2015
Revenues:				
License and milestone fees	\$ 76	\$ 5,086	\$ 26,915	\$ 57,815
Non-cash royalty revenue	5,944	5,461	25,299	5,461
Royalty revenue	-	, _	195	13,890
Research and development support	1,335	708	4,014	2,848
Clinical materials revenue	53	1,356	3,579	5,527
Total revenues	7,408	12,611	60,002	85,541
Expenses:				
Research and development	37,490	30,437	146,915	111,768
General and administrative	9,298	7,261	36,916	28,228
Total operating expenses	46,788	37,698	183,831	139,996
Loss from operations	(39,380)	(25,087)	(123,829)	(54,455)
Non-cash interest expense on liability related to sale of future				
royalty & convertible bonds	(4,956)	(5,436)	(20,130)	(5,436)
Other (expense) income, net	(424)	49	304	(848)
Net loss	<u>\$ (44,760)</u>	<u>\$ (30,474)</u>	<u>\$(143,655)</u>	<u>\$ (60,739)</u>

Net loss per common share, basic and diluted	<u>\$ (0.51)</u>	<u>\$ (0.35)</u>	<u>\$ (1.65)</u>	<u>\$ (0.71)</u>
Weighted average common shares outstanding, diluted	87,062	86,269	86,976	86,038

View source version on <u>businesswire.com</u>: <u>http://www.businesswire.com/news/home/20160804005174/en/</u>

For Investors: ImmunoGen, Inc. Carol Hausner, 781-895-0600 info@immunogen.com or For Media: Michael Lampe, 484-575-5040 michael@scientpr.com

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