



## ImmunoGen Reports Recent Progress and Second Quarter 2019 Financial Results

August 2, 2019

*Registration Study for Mirvetuximab Soravtansine in Ovarian Cancer on Track to Start by Year-End*

*Full Data from the Phase 3 FORWARD I Trial and Initial FORWARD II Triplet Data to be Presented at ESMO*

*Recommended Phase 2 Dose and Schedule for IMG632 Determined; Combination and MRD+ Protocol Filed*

*Updated 2019 Financial Guidance Provided*

*Conference Call to be Held at 8:00 a.m. ET Today*

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 2, 2019-- [ImmunoGen, Inc.](http://www.immunogen.com), (Nasdaq: IMGN), a leader in the expanding field of antibody-drug conjugates (ADCs) for the treatment of cancer, today reviewed recent progress in the business and reported financial results for the quarter ended June 30, 2019.

"In the second quarter, we took important steps towards finalizing the design of the registration study for mirvetuximab soravtansine in folate receptor alpha (FR $\alpha$ )-high platinum-resistant ovarian cancer, prioritizing our portfolio of earlier-stage product candidates, and extending our cash runway with the completion of our operational review," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "Over the back half of 2019, we plan to meet with regulators regarding the final design of the registration study for mirvetuximab with the goal of initiating enrollment by end of year. Additionally, we look forward to presenting the full FORWARD I data and initial FORWARD II triplet data evaluating mirvetuximab in combination with carboplatin and Avastin<sup>®</sup> (bevacizumab) at ESMO."

Enyedy continued, "In parallel, we have determined a recommended Phase 2 dose and schedule for IMG632 and filed a protocol to support combination studies, as well as evaluate single-agent safety and efficacy in acute myeloid leukemia (AML) patients with minimal residual disease (MRD+) following frontline induction therapy. With the benefit of approximately \$240 million on the balance sheet and the completion of our operational review, we are in a strong financial position to execute across our prioritized portfolio."

### RECENT PROGRESS

- Presented mature data demonstrating significant anti-tumor activity, as well as favorable safety and tolerability, from the FORWARD II expansion cohort evaluating mirvetuximab in combination with bevacizumab in patients with FR $\alpha$ -positive platinum-resistant ovarian cancer at the American Society of Clinical Oncology (ASCO) Annual Meeting in June.
- Accelerated enrollment in the FORWARD II mirvetuximab plus bevacizumab combination cohort in ovarian cancer patients for whom a non-platinum-based regimen would be an appropriate next therapy.
- Determined the recommended Phase 2 dose and schedule for IMG632 and filed the protocol to initiate combination studies with Vidaza<sup>®</sup> (azacitidine) and Venclexta<sup>®</sup> (venetoclax) in relapsed/refractory AML patients and to evaluate IMG632 in MRD+ patients following frontline induction therapy.
- Continued enrollment in the Phase 1 expansion study of IMG632 in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- Advanced IND-enabling activities for IMGC936, a novel ADAM9-targeting ADC in co-development with MacroGenics.
- Completed operational review expected to extend the Company's cash runway through the readout of the mirvetuximab pivotal study in platinum-resistant ovarian cancer.

### ANTICIPATED UPCOMING EVENTS

- Meet with the United States Food and Drug Administration (FDA) and European Medicines Agency (EMA) in the second half of this year to review the design of the next Phase 3 study of mirvetuximab soravtansine.
- Complete enrollment in the FORWARD II mirvetuximab plus bevacizumab combination cohort in the third quarter.
- Present full FORWARD I data (oral presentation) and initial FORWARD II triplet data (poster presentation) at the European Society for Medical Oncology (ESMO) Congress in late September.
- Initiate the Phase 3 registration study of mirvetuximab as a monotherapy for women with FR $\alpha$ -high, platinum-resistant ovarian cancer by the end of this year.
- Commence enrollment in the IMG632 combination and single-agent MRD+ Phase 2 cohorts.
- Present preclinical combination and updated monotherapy data for IMG632 at the American Society of Hematology (ASH) Congress.

### FINANCIAL RESULTS

Revenues for the quarter ended June 30, 2019 were \$15.5 million, compared with \$9.3 million for the quarter ended June 30, 2018. Revenues in the second quarter of 2019 included \$10.4 million in non-cash royalty revenues, compared with \$7.2 million for the second quarter of 2018. License and milestone fees of \$5.1 million for the second quarter of 2019 included recognition and receipt of a \$5 million milestone pursuant to a license agreement

with Genentech, a member of the Roche Group, compared to \$1.3 million of upfront license fees recognized in the second quarter of 2018. Revenues for the prior year period also included \$0.4 million of research and development (R&D) support fees and \$0.3 million of clinical materials revenue, compared with \$0.1 million of similar fees earned in the current period.

Operating expenses for the second quarter of 2019 were \$56.6 million, compared with \$48.0 million for the same quarter in 2018. The increase was driven by a \$19.3 million restructuring charge recorded in the current period resulting from the operational changes announced on June 27, 2019, which includes a one-time severance charge, retention costs, and losses recorded on laboratory equipment, compared to a \$0.7 million charge recorded in the second quarter of 2018 related to the decommissioning of the Company's Norwood facility. R&D expenses were \$28.6 million in the second quarter of 2019, compared with \$38.7 million for the second quarter of 2018. This decrease was primarily due to lower personnel expenses driven by adjustments made in the current quarter to bonus and stock compensation expense as a result of the restructuring of the business, lower clinical trial costs in the current period driven by patient enrollment in the FORWARD I Phase 3 clinical trial during the prior year period, and lower external manufacturing costs. General and administrative expenses were flat at \$8.7 million in the second quarter of both 2019 and 2018.

ImmunoGen reported a net loss of \$43.4 million, or \$0.29 per basic and diluted share, for the second quarter of 2019, compared with a net loss of \$41.6 million, or \$0.31 per basic and diluted share, for the same quarter last year. Weighted average shares outstanding increased to 148.1 million from 134.4 million in those quarters.

ImmunoGen had \$239.8 million in cash and cash equivalents as of June 30, 2019, compared with \$262.3 million as of December 31, 2018, and had \$2.1 million of convertible debt outstanding in each period. Cash used in operations was \$20.8 million for the first six months of 2019, compared with cash used in operations of \$85.3 million for the same period in 2018. The current period benefited from \$65.2 million of net proceeds generated from the sale of the Company's residual rights to Kadcyła<sup>®</sup> (ado-trastuzumab emtasine) royalties in January 2019. Capital expenditures were \$2.4 million and \$2.1 million for the first six months of 2019 and 2018, respectively.

## FINANCIAL GUIDANCE

Following the completion of its operational review in June 2019, ImmunoGen has updated its financial guidance for 2019 as follows:

- revenues between \$40 million and \$45 million;
- operating expenses between \$175 million and \$180 million; and
- cash and cash equivalents at December 31, 2019, between \$165 million and \$170 million.

ImmunoGen expects that its current cash, together with expense reductions resulting from the operational changes previously announced and anticipated cash receipts from partners, will fund operations through the release of top-line results from the upcoming mirvetuximab Phase 3 study in platinum-resistant ovarian cancer, which are expected in the first half of 2022.

## CONFERENCE CALL INFORMATION

ImmunoGen will hold a conference call today at 8:00 a.m. ET to discuss these results. To access the live call by phone, dial +1-323-794-2093; the conference ID is 9100112. The call may also be accessed through the Investors and Media section of the Company's website at [www.immunogen.com](http://www.immunogen.com).

## ABOUT IMMUNOGEN

ImmunoGen is developing the next generation of antibody-drug conjugates (ADCs) to improve outcomes for cancer patients. By generating targeted therapies with enhanced anti-tumor activity and favorable tolerability profiles, we aim to disrupt the progression of cancer and offer our patients more good days. We call this our commitment to "target a better now."

Learn more about who we are, what we do, and how we do it at [www.immunogen.com](http://www.immunogen.com).

*Avastin<sup>®</sup>, Vidaza<sup>®</sup>, Venclexta<sup>®</sup>, and Kadcyła<sup>®</sup> are registered trademarks of their respective owners.*

## FORWARD-LOOKING STATEMENTS

*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 occurrence, timing, and outcome of potential pre-clinical, clinical, and regulatory events related to the Company's 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 results of communications with FDA, risks and uncertainties related to the execution of the restructuring of the Company's operations, the Company's ability to control future spending to enable it to fund its remaining operations through the release of top-line results from the upcoming mirvetuximab pivotal study, as well as the risks and uncertainties inherent in the Company's development programs, including clinical studies and regulatory processes, their timings and results. A review of these risks can be found in ImmunoGen's Annual Report on Form 10-K for the year ended December 31, 2018 and other reports filed with the Securities and Exchange Commission.*

## SELECTED FINANCIAL INFORMATION

(in thousands, except per share amounts)

## CONDENSED CONSOLIDATED BALANCE SHEETS

**(Unaudited)**

	<b>June 30,</b>	<b>December 31,</b>
	<b>2019</b>	<b>2018</b>
<b>ASSETS</b>		
Cash and cash equivalents	\$ 239,825	\$ 262,252
Other assets	47,844	33,129
Total assets	\$ 287,669	\$ 295,381
<b>LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY</b>		
Current portion of deferred revenue	\$ 317	\$ 317
Other current liabilities	74,299	70,343
Long-term portion of deferred revenue	145,614	80,485
Other long-term liabilities	135,613	133,264
Shareholders' (deficit) equity	(68,174 )	10,972
Total liabilities and shareholders' (deficit) equity	\$ 287,669	\$ 295,381

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

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
<b>Revenues:</b>				
Non-cash royalty revenue	\$ 10,412	\$ 7,242	\$ 18,900	\$ 14,432
License and milestone fees	5,079	1,321	5,158	12,861
Research and development support	51	388	68	771
Clinical materials revenue	-	336	-	1,038
Total revenues	15,542	9,287	24,126	29,102

Expenses:

Research and development	28,559	38,701	67,452	83,532
General and administrative	8,700	8,652	19,478	18,647
Restructuring charge	19,342	686	19,901	2,417
Total operating expenses	56,601	48,039	106,831	104,596
Loss from operations	(41,059 )	(38,752 )	(82,705 )	(75,494 )
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(3,818 )	(2,611 )	(7,250 )	(5,657 )
Interest expense on convertible bonds	(23 )	(23 )	(47 )	(47 )
Other income (loss), net	1,454	(238 )	2,805	961
Net loss	\$ (43,446 )	\$ (41,624 )	\$ (87,197 )	\$ (80,237 )
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.29 )</b>	<b>\$ (0.31 )</b>	<b>\$ (0.59 )</b>	<b>\$ (0.61 )</b>
<b>Basic and diluted weighted average common shares outstanding</b>	<b>148,129</b>	<b>134,384</b>	<b>147,972</b>	<b>132,512</b>

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Source: ImmunoGen, Inc.

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