



ImmunoGen Reports Recent Progress and Third Quarter 2019 Financial Results

November 1, 2019

Full Mirvetuximab Soravtansine Phase 3 FORWARD I and Initial Phase 1b FORWARD II Triplet Data Presented at ESMO

Phase 3 MIRASOL Trial for Mirvetuximab in Ovarian Cancer on Track to Start by Year-End

Updated IMG632 AML and BPDCN Monotherapy Data Accepted as Oral Presentation at ASH

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

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 1, 2019-- [ImmunoGen, Inc.](https://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 September 30, 2019.

"The FORWARD I analyses presented at ESMO have provided us with valuable insights into the patients who benefit most from mirvetuximab," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "We have since met with FDA to review these data and the design of MIRASOL, the Phase 3 study of mirvetuximab for platinum-resistant ovarian cancer patients whose tumors express high levels of folate receptor alpha. We anticipate enrolling our first patient before year-end and, on the strength of the data we have generated in the program, believe we have increased the likelihood of a positive outcome with this next study."

Enyedy added, "IMG632 continues to make encouraging progress in the clinic, with the initiation of combination studies in relapsed/refractory AML patients and monotherapy expansion into relapsed ALL and MRD+ AML patients following frontline induction therapy. We exit the year with significant momentum across our portfolio with an oral presentation for IMG632 at ASH, ongoing studies for mirvetuximab combination regimens, advances in our early-stage pipeline, and a strong financial position to execute against our strategic priorities."

RECENT PROGRESS

- Presented full data and additional exploratory analyses from the Phase 3 FORWARD I study evaluating mirvetuximab compared to chemotherapy in women with folate receptor alpha (FR α)-positive, platinum-resistant ovarian cancer at the European Society for Medical Oncology (ESMO) Congress.
- Presented initial safety and overall response data from the Phase 1b FORWARD II triplet cohort evaluating mirvetuximab in combination with carboplatin and Avastin[®] (bevacizumab) in patients with recurrent, platinum-sensitive ovarian cancer at ESMO.
- Met with the United States Food and Drug Administration (FDA) to review the design of MIRASOL, the Phase 3 study evaluating mirvetuximab as monotherapy for women with FR α -high, platinum-resistant ovarian cancer.
- Completed enrollment in the FORWARD II mirvetuximab plus bevacizumab combination cohort in "platinum agnostic" ovarian cancer patients for whom a non-platinum-based regimen would be an appropriate next therapy.
- For IMG632 monotherapy, continued enrollment in the Phase 1 expansion cohorts in patients with acute myeloid leukemia (AML) and blastic plasmacytoid dendritic cell neoplasm (BPDCN), opened an expansion cohort now enrolling patients with relapsed acute lymphocytic leukemia (ALL), and initiated a study in minimal residual disease positive (MRD+) AML patients following frontline induction therapy.
- For IMG632 combination therapy, initiated studies with Vidaza[®] (azacitidine) and Venclexta[®] (venetoclax) in relapsed/refractory unfit AML patients.
- Advanced investigational new drug (IND)-enabling activities for IMGC936, a novel ADAM9-targeting ADC in co-development with MacroGenics.

ANTICIPATED UPCOMING EVENTS

- Initiate MIRASOL by year-end.
- Present preclinical combination data (poster presentation) and updated clinical monotherapy data (oral presentation) for IMG632 with additional patients enrolled in AML and BPDCN expansion cohorts at the American Society of Hematology (ASH) Annual Meeting in December.
- Continue enrollment in IMG632 combination and single-agent BPDCN, relapsed AML, MRD+ AML, and relapsed ALL expansion cohorts.
- IND filing for IMGC936 in the first half of 2020.
- Present initial data from FORWARD II platinum agnostic and updated triplet combination studies in mid-2020.
- Transition next generation anti-FR α ADC, IMG151, to pre-clinical development in mid-2020.

FINANCIAL RESULTS

Revenues for the quarter ended September 30, 2019 were \$13.3 million, compared with \$10.9 million for the quarter ended September 30, 2018. Revenues in the third quarter of 2019 included \$13.2 million in non-cash royalty revenues, compared with \$8.4 million for the third quarter of 2018.

Revenues for the prior year period also included \$0.7 million of license and milestone fees, inclusive of a \$0.5 million milestone pursuant to a license agreement with Fusion Pharmaceuticals, \$0.4 million of research and development (R&D) support fees, and \$1.4 million of clinical materials revenue, compared with \$0.1 million of similar fees earned in the current period.

Operating expenses for the third quarter of 2019 were \$31.2 million, compared with \$56.5 million for the same quarter in 2018. The decrease was driven by R&D expenses, which were \$21.0 million in the third quarter of 2019 compared with \$47.2 million for the third quarter of 2018. This decrease was primarily due to: lower expenses resulting from the restructuring of the business at the end of the second quarter of 2019, including decreases in personnel and third-party research expenses and lower facility-related allocations; a decrease in clinical trial expenses in the current period driven by greater activity in the FORWARD I Phase 3 clinical trial during the prior year period; and lower external manufacturing costs driven by activity to support commercial validation of mirvetuximab in the prior year period. General and administrative expenses in the third quarter of 2019 were \$9.2 million, compared to \$8.3 million in the third quarter of 2018, primarily due to a higher allocation of facility-related expenses for excess laboratory and office space resulting from the recent restructuring. Operating expenses for the third quarter of 2019 also included a \$1.0 million charge related primarily to retention costs resulting from the restructuring, compared to a \$0.9 million charge recorded in the third quarter of 2018 related to the decommissioning of the Company's Norwood facility.

ImmunoGen reported a net loss of \$21.8 million, or \$0.15 per basic and diluted share, for the third quarter of 2019, compared with a net loss of \$46.8 million, or \$0.32 per basic and diluted share, for the same quarter last year. Weighted average shares outstanding increased to 148.5 million from 147.2 million in those quarters.

ImmunoGen had \$204.5 million in cash and cash equivalents as of September 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 \$55.8 million for the first nine months of 2019, compared with cash used in operations of \$125.1 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 Kadcyra[®] (ado-trastuzumab emtasine) royalties in January 2019. Capital expenditures were \$2.8 million and \$4.2 million for the first nine months of 2019 and 2018, respectively.

FINANCIAL GUIDANCE

ImmunoGen has updated its financial guidance for 2019 as follows:

- revenues between \$65 million and \$70 million;
- operating expenses between \$170 million and \$175 million; and
- cash and cash equivalents at December 31, 2019, between \$170 million and \$175 million.

Revenue guidance has been updated to reflect recognition of deferred revenue under our Jazz Pharmaceuticals collaboration related to IMG779, which was discontinued as part of ImmunoGen's portfolio prioritization exercise in June of this year. 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 MIRASOL, 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 (877) 621-5803; the conference ID is 8865657. The call may also be accessed through the Investors and Media section of immunogen.com. Following the call, a replay will be available at the same location.

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.

Avastin[®], Vidaza[®], Venclexta[®], and Kadcyra[®] 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 Company's revenues and operating expenses for the twelve months ending December 31, 2019; its cash and marketable securities as of December 31, 2019; the occurrence, timing, and outcome of potential pre-clinical, clinical, and regulatory events related to the Company's product candidates; and the presentation of pre-clinical and clinical data on 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 outcome of the Company's clinical development processes; the difficulties inherent in the development of novel pharmaceuticals, including uncertainties as to the timing, expense, and results of pre-clinical studies, clinical trials, and regulatory processes; the Company's ability to financially support its product programs; and other factors more fully described 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.

IMMUNOGEN, INC.

SELECTED FINANCIAL INFORMATION

(in thousands, except per share amounts)

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30,	December 31,
	2019	2018
ASSETS		
Cash and cash equivalents	\$ 204,491	\$ 262,252
Other assets	49,645	33,129
Total assets	\$ 254,136	\$ 295,381
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current portion of deferred revenue	\$ 14,817	\$ 317
Other current liabilities	73,357	70,343
Long-term portion of deferred revenue	131,035	80,485
Other long-term liabilities	121,152	133,264
Shareholders' (deficit) equity	(86,225)	10,972
Total liabilities and shareholders' (deficit) equity	\$ 254,136	\$ 295,381

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Non-cash royalty revenue	\$ 13,202	\$ 8,441	\$ 32,102	\$ 22,873
License and milestone fees	79	672	5,237	13,533
Research and development support	-	388	68	1,159
Clinical materials revenue	-	1,427	-	2,465
Total revenues	13,281	10,928	37,407	40,030
Expenses:				
Research and development	21,015	47,243	88,467	130,775

General and administrative	9,208	8,347	28,686	26,994
Restructuring charge	1,020	870	20,921	3,287
Total operating expenses	31,243	56,460	138,074	161,056
Loss from operations	(17,962)	(45,532)	(100,667)	(121,026)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(4,275)	(2,546)	(11,525)	(8,203)
Interest expense on convertible bonds	(24)	(23)	(71)	(70)
Other income (loss), net	511	1,294	3,316	2,255
Net loss	\$ (21,750)	\$ (46,807)	\$ (108,947)	\$ (127,044)
Basic and diluted net loss per common share	\$ (0.15)	\$ (0.32)	\$ (0.74)	\$ (0.92)
Basic and diluted weighted average common shares outstanding	148,479	147,220	148,143	137,472

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Source: ImmunoGen, Inc.

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