ImmunoGen Reports Recent Progress and Third Quarter 2022 Financial Results

November 4, 2022

Launch Preparations Completed Ahead of November 28, 2022 PDUFA Date

Presentations at ESMO, IGCS, and ESGO Highlight Mirvetuximab's Potential to Become New Standard of Care and Combination Agent of Choice in FRα-Positive Ovarian Cancer

Initial Data from Pivotal Phase 2 CADENZA Study Demonstrated Encouraging Activity and Favorable Tolerability of Pivekimab Sunirine in Frontline BPDCN

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

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 4, 2022-- ImmunoGen, Inc. (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, 2022.

"With approval expected on or before our November 28, 2022 PDUFA date, we have completed our preparations to launch mirvetuximab this month," said Mark Enyedy, ImmunoGen's President and Chief Executive Officer. "Our commercial and medical teams are in the field, our distribution network is in place, and our patient support infrastructure is ready to deliver mirvetuximab to ovarian cancer patients with platinum-resistant FRα-positive disease."

Enyedy continued, "Top-line data from the ongoing MIRASOL study are expected in early 2023, and we advanced the broader mirvetuximab program with the initiation of the GLORIOSA and 0420 studies to further explore its potential in platinum-sensitive disease. Turning to pivekimab, our second pivotal program, we reported encouraging initial data from the CADENZA study in frontline BPDCN and look forward to presenting initial data from our triplet expansion cohorts in AML in an oral presentation at ASH. We are also progressing our earlier-stage portfolio and expect to share initial data for IMGN936 and to enroll the first patient in the IMGN151 trial before year-end. With an intense focus on execution, we are well positioned to transform ImmunoGen into a fully-integrated oncology company this year."

RECENT PROGRESS

- Presented additional data from the mirvetuximab program at the 2022 European Society for Medical Oncology (ESMO) Congress, the 2022 Annual Global Meeting of the International Gynecologic Cancer Society (IGCS), and the 23rd Congress of the European Society of Gynaecological Oncology (ESGO)
- Advanced accrual in PICCOLO, a single-arm study of mirvetuximab monotherapy in folate receptor alpha (FRα)-high recurrent platinum-sensitive ovarian cancer.
- Initiated two combination studies for mirvetuximab in platinum-sensitive ovarian cancer: Trial 0420, a single-arm Phase 2 trial of mirvetuximab in combination with carboplatin followed by mirvetuximab continuation in FRα-low, medium, and high patients; and GLORIOSA, a randomized Phase 3 trial of mirvetuximab in combination with bevacizumab maintenance in FRα-high recurrent second-line platinum-sensitive ovarian cancer.
- Supported investigator-sponsored trials of mirvetuximab plus carboplatin in a single-arm study in the neoadjuvant setting and a randomized study in patients with recurrent platinum-sensitive ovarian cancer.
- Reported initial data from the pivotal Phase 2 CADENZA study of pivekimab sunirine (pivekimab) in frontline de novo blastic plasmacytoid dendritic cell neoplasm (BPDCN) and in BPDCN patients with a prior or concomitant hematologic malignancy (PCHM).
- Presented efficacy data for the pivekimab triplet with Vidaza® (azacitidine) and Venclexta® (venetoclax) in genetic sub-types of acute myeloid leukemia (AML) at the Society of Hematologic Oncology (SOHO) Annual Meeting.
- Continued enrollment in expansion cohorts in the Phase 1b/2 study evaluating pivekimab, azacitidine, and venetoclax in both relapsed and frontline unfit AML patients.
- Advanced dose escalation and opened additional sites in the Phase 1 study of IMGC936 in multiple solid tumor types.
- Initiated Phase 1 study of IMGN151, the Company's next-generation FRα-targeting ADC.

ANTICIPATED UPCOMING EVENTS

- Obtain accelerated approval of mirvetuximab for FRα-positive platinum-resistant ovarian cancer.
- Present initial data from relapsed and frontline unfit AML expansion cohorts combining pivekimab, azacitidine, and venetoclax in an oral presentation at the 2022 American Society of Hematology (ASH) Annual Meeting in December.
- Complete dose-escalation in the Phase 1 study evaluating IMGC936, with initial data anticipated before year-end.
- Publish SORAYA data and data on mirvetuximab in combination with bevacizumab in peer-reviewed journals.
- Submit data covering mirvetuximab monotherapy and mirvetuximab in combination with bevacizumab regimens for potential inclusion in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines by early 2023.
- Report top-line data for MIRASOL in early 2023.

- Present efficacy data from the SORAYA trial by sequence of treatment at the Society of Gynecologic Oncology (SGO) 2023 Annual Meeting.

FINANCIAL RESULTS

Total revenues were $15.4 million for the quarter ended September 30, 2022 compared to $9.2 million for the quarter ended September 30, 2021. The increase was due to greater license and milestone fee revenue driven by fees recognized pursuant to license agreements with Lilly and Novartis and higher non-cash royalty revenue.

Operating expenses for the quarter ended September 30, 2022 were $92.8 million, compared with $43.4 million for the same quarter in 2021. Research and development expenses rose to $59.2 million for the quarter ended September 30, 2022 compared to $33.1 million for the quarter ended September 30, 2021, driven by increases in personnel and temporary staffing costs, contract services, and external manufacturing costs largely incurred in anticipation of a potential US launch of mirvetuximab, as well as greater clinical trial costs. Selling, general, and administrative expenses increased to $33.6 million for the quarter ended September 30, 2022 compared to $10.3 million for the quarter ended September 30, 2021, due primarily to building commercial capabilities, including the hiring of personnel, in preparation for a potential US launch of mirvetuximab.

Net loss for the third quarter of 2022 was $77.8 million, or $0.31 per basic and diluted share, compared to a net loss of $37.3 million, or $0.18 per basic and diluted share, for the third quarter of 2021. Weighted average shares outstanding increased to 253.5 million for the 2022 period from 204.8 million in the prior year.

ImmunoGen had $309.5 million in cash and cash equivalents as of September 30, 2022, compared with $478.8 million as of December 31, 2021. Cash used in operations was $169.6 million for the first nine months of 2022, compared with cash used in operations of $123.5 million for the same period in 2021. Capital expenditures were $1.1 million in each of the nine months ended September 30, 2022 and 2021.

FINANCIAL GUIDANCE

ImmunoGen has updated its financial guidance for 2022 and now expects:

- revenues between $80 million and $90 million;
- operating expenses between $320 million and $330 million; and
- cash and cash equivalents at December 31, 2022 to be between $230 million and $240 million.

Revenue guidance does not reflect potential product sales from mirvetuximab.

The increase in operating expense guidance is largely attributable to faster than expected hiring, preparation for commercialization, and strong clinical trial startup and execution.

ImmunoGen expects that its current cash, combined with anticipated product and collaboration revenues, will fund operations into 2024.

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, please register here. A dial-in and unique PIN will be provided to join the call. The call may also be accessed through the Investors and Media section of the Company's website, www.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.

Vidaza® and Venclexta® are registered trademarks of their respective owners.

FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These statements include, but are not limited to, ImmunoGen's expectations related to: the Company's revenues and operating expenses for 2022 and its cash and cash equivalents as of December 31, 2022; the Company's anticipated cash runway; the occurrence, timing, and outcome of potential preclinical, clinical, and regulatory events related to, and the potential benefits of, the Company's product candidates, including, but not limited to the outcome of the FDA's review of the Company's BLA for mirvetuximab, the commercial launch of mirvetuximab, the potential expanded uses of mirvetuximab, mirvetuximab becoming a standard of care for FRα-positive ovarian cancer patients and combination agent of choice, the initiation of Trial 0420 and the GLORIOSA Phase 3 trial, the enrollment of patients in the expansion cohorts combining pivekimab, azacitidine, and venetoclax in frontline and relapsed AML, and the completion of the dose-escalation Phase 1 study evaluating IMGC936; the timing and presentation of preclinical and clinical data on the Company's product candidates, including initial data from relapsed and frontline unfit AML expansion cohorts combining pivekimab, azacitidine, and venetoclax, top-line data for the MIRASOL study, SORAYA data and data on mirvetuximab in combination with bevacizumab, including SORAYA data to be presented at SGO in 2023, and initial data from the Phase 1 dose-escalation study evaluating IMGC936; and the Company's business and product development strategies. 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 preclinical and clinical development processes; the results of the ongoing MIRASOL trial may fail to support full approval of mirvetuximab and, if not, additional studies may be required; 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; the timing and outcome of the Company's anticipated interactions with regulatory authorities, including that the FDA may determine that our BLA for mirvetuximab does not meet the conditions for accelerated approval; the risk that we may not

be able to obtain adequate price and reimbursement for any approved products, including the potential for delays or additional difficulties for mirvetuximab if the FDA grants accelerated approval; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and the resulting impact on ImmunoGen's industry and business; and other factors as set forth in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022, the Company's Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission on May 6, 2022 and August 1, 2022, and other reports filed with the Securities and Exchange Commission, and other reports filed with the Securities and Exchange Commission. The forward-looking statements in this press release speak only as of the date of this press release. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments, or otherwise, except as may be required by applicable law.

SELECTED FINANCIAL INFORMATION
(in thousands, except per share amounts)
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2022	December 31, 2021
ASSETS		
Cash and cash equivalents	$ 309,511	$ 478,750
Other assets	49,288	47,015
Total assets	$ 358,799	$ 525,765
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	$ 15,079	$ 44,351
Other current liabilities	88,563	56,594
Long-term portion of deferred revenue	38,732	47,717
Other long-term liabilities	38,418	51,517
Shareholders' equity	178,007	325,586
Total liabilities and shareholders' equity	$ 358,799	$ 525,765

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
License and milestone fees	$ 7,382	$ 2,677	$ 45,247	$ 3,086
Non-cash royalty revenue	7,993	6,533	21,537	38,768
Research and development support	-	-	831	10
Total revenues	15,375	9,210	67,615	41,864
Expenses:				
Research and development	59,181	33,147	154,885	102,149
Selling, general and administrative	33,623	10,297	74,064	30,234
Total operating expenses	92,804	43,444	228,949	132,383
Loss from operations	(77,429)	(34,234)	(161,334)	(90,519)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(867)	(2,751)	(3,194)	(10,952)
Interest expense on convertible bonds	-	-	-	(47)
Other income (loss), net	541	(354)	607	(613)
Net loss	$ (77,755)	$ (37,339)	$(163,921)	$(102,131)
Basic and diluted net loss per common share	**$ (0.31)**	**$ (0.18)**	**$ (0.65)**	**$ (0.51)**

Basic and diluted weighted average common shares outstanding	**253,511**	**204,844**	**253,371**	**201,212**

View source version on businesswire.com: https://www.businesswire.com/news/home/20221104005146/en/

INVESTOR RELATIONS
ImmunoGen
Anabel Chan
781-895-0600
anabel.chan@immunogen.com

MEDIA
ImmunoGen
Courtney O'Konek
781-895-0600
courtney.okonek@immunogen.com

OR

FTI Consulting
Robert Stanislaro
212-850-5657
robert.stanislaro@fticonsulting.com

Source: ImmunoGen, Inc.