ImmunoGen Reports Recent Progress and Second Quarter 2022 Financial Results

July 29, 2022

BLA for Mirvetuximab Soravtansine Monotherapy in Ovarian Cancer Accepted by FDA with Priority Review; PDUFA Date Set for November 28, 2022

Completed enrollment in the Confirmatory MIRASOL Study

Presented Additional Efficacy and Safety Data for Mirvetuximab Monotherapy at ASCO; Poster Highlighting Updated SORAYA Data Selected for Best of ASCO® Program

Announced Multi-Year Collaboration with Oxford BioTherapeutics to Research and Develop Novel ADCs

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

WALTHAM, Mass.--(BUSINESS WIRE)--Jul. 29, 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 June 30, 2022.

“With the BLA for MIRV accepted and receiving Priority Review designation from FDA, we have taken a significant step closer to bringing this important new therapy to ovarian cancer patients this year,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer, “We are pleased with the positive reception our data received at ASCO and are focused on building our commercial and medical infrastructure to support a successful launch to establish MIRV as the new standard of care for patients with folate receptor alpha positive disease.”

Enyedy continued, “We have also completed accrual in MIRASOL and expect to report data from this confirmatory study early next year. In support of moving MIRV into broader patient populations, we are expanding our development program and are in the process of initiating the GLORIOSA and Trial 0420 studies. Turning to our second pivotal program, PVEK, we expect to report preliminary efficacy data from our pivotal CADENZA study in BPDCN this year and plan to present initial data from our triplet expansion cohort in AML at ASH. We have had a productive first half of the year, and with key regulatory and clinical milestones anticipated before year-end, we are well positioned to create meaningful value for both patients and shareholders.”

RECENT PROGRESS

- Announced that the U.S. Food and Drug Administration (FDA) accepted and filed the Biologics License Application (BLA) for mirvetuximab soravtansine (mirvetuximab) monotherapy in patients with folate receptor alpha (FRα)-high platinum-resistant ovarian cancer who have been previously treated with one to three prior systemic treatments with Priority Review designation.
- Completed enrollment in the confirmatory MIRASOL study.
- Presented additional efficacy data from the pivotal SORAYA study and an integrated safety summary of single-agent mirvetuximab across multiple studies enrolling almost 500 patients with FRα-positive recurrent ovarian cancer at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in June.
- Advanced accrual in PICCOLO, a single-arm study of mirvetuximab monotherapy in FRα-high recurrent 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.
- Progressed the pivotal Phase 2 CADENZA study of pivekimab sunirine (pivekimab) in frontline and relapsed/refractory (R/R) blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- Continued enrollment in expansion cohorts in the Phase 1b/2 study evaluating pivekimab, Vidaza® (azacitidine), and Venclexta® (venetoclax) in both R/R and frontline unfit acute myeloid leukemia (AML) patients.
- Advanced dose escalation and opened additional sites in the Phase 1 study of IMGC936 in multiple solid tumor types.
- Progressed the generation of supplemental chemistry, manufacturing, and controls (CMC) information for submission to the FDA to support the investigational new drug (IND) application for IMGN151.
- Announced a multi-year collaboration to research novel, first-in-class ADCs with Oxford BioTherapeutics (OBT) utilizing ImmunoGen's proprietary linker-payload technology directed to novel targets identified via OBT's proprietary OGAP® discovery platform.

ANTICIPATED UPCOMING EVENTS

- Potential FDA approval of mirvetuximab as a monotherapy in patients with FRα-high platinum-resistant ovarian cancer by the Prescription Drug User Fee Act (PDUFA) action date of November 28, 2022.
- Generate top-line data for MIRASOL in early 2023.
- Enroll the first patients in 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.
- Present additional data from the mirvetuximab program at the 2022 European Society for Medical Oncology (ESMO) Congress and the 2022 Annual Global Meeting of the International Gynecologic Cancer Society (IGCS) in September.
- Report preliminary efficacy data from the pivotal CADENZA study of pivekimab in BPDCN before year-end.
- Present pivekimab efficacy data for genetic sub-types of AML at the Society of Hematologic Oncology (SOHO) in September, and initial data from frontline and R/R AML expansion cohorts combining pivekimab, azacitidine, and venetoclax 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.
- Begin enrollment in the Phase 1 study of IMGN151 following the submission of supplemental CMC information to the FDA.

FINANCIAL RESULTS

Total revenues were $14.2 million for the quarter ended June 30, 2022 compared to $16.9 million for the quarter ended June 30, 2021. The decrease was driven by lower non-cash royalty revenue due to the completion of the first tranche of payments under the 2015 KADCYLA® royalty agreement in the second quarter of 2021, partially offset by greater license and milestone fee revenue driven by the recognition of $6.9 million of fees previously received and deferred pursuant to the Company's collaboration agreement with Huadong Medicine.

Operating expenses for the quarter ended June 30, 2022 were $75.2 million, compared with $44.3 million for the same quarter in 2021. Research and development expenses rose to $51.4 million for the quarter ended June 30, 2022 compared to $34.6 million for the quarter ended June 30, 2021, driven by increases in clinical trial costs, personnel and temporary staffing costs, and research expenses to further build our ADC pipeline, which includes a $7.5 million upfront fee paid to Oxford BioTherapeutics. Selling, general and administrative expenses increased to $23.8 million for the quarter ended June 30, 2022 compared to $9.7 million for the quarter ended June 30, 2021, due primarily to building commercial capabilities, including the hiring of personnel, in anticipation of a potential U.S. launch of mirvetuximab in the fourth quarter of 2022.

Net loss for the second quarter of 2022 was $62.0 million, or $0.24 per basic and diluted share, compared to a net loss of $30.7 million, or $0.15 per basic and diluted share, for the second quarter of 2021. Weighted average shares outstanding increased to 253.3 million for the 2022 period from 199.9 million in the prior year.

ImmunoGen had $373.9 million in cash and cash equivalents as of June 30, 2022, compared with $478.8 million as of December 31, 2021. Cash used in operations was $105.4 million for the first six months of 2022, compared with cash used in operations of $88.5 million for the same period in 2021, with the current period benefiting from a $13.0 million upfront license payment received from Lilly. Capital expenditures were $0.5 million and $0.9 million for the first six months of 2022 and 2021, respectively.

FINANCIAL GUIDANCE

ImmunoGen's financial guidance for 2022 remains unchanged; the Company continues to expect:

- revenues between $75 million and $85 million;
- operating expenses between $285 million and $295 million; and
- cash and cash equivalents at December 31, 2022 to be between $245 million and $255 million.

Given the range in timing for potential approval, revenue guidance does not reflect potential product sales from mirvetuximab.

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.

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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 enrollment of patients in Trial 0420, the GLORIOSA Phase 3 trial, and the expansion cohorts combining pivekimab, azacitidine, and venetoclax in frontline and relapsed AML, the completion of the dose-escalation Phase 1 study evaluating IMGC936 and the dosing of patients in a Phase 1 study for IMGN151; the timing and presentation of preclinical and clinical data on the Company's product candidates, including additional data from the mirvetuximab program, pivekimab efficacy data for genetic sub-types of AML, top-line data for the MIRASOL study, top-line data from the CADENZA study, initial data from the frontline and relapsed AML expansion cohorts, 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 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; 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, 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.

IMMUNOGEN, INC.

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

CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2022	December 31, 2021
ASSETS		
Cash and cash equivalents	$ 373,874	$ 478,750
Other assets	48,421	47,015
Total assets	$ 422,295	$ 525,765
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	$ 15,636	$ 44,351
Other current liabilities	71,435	56,594
Long-term portion of deferred revenue	43,611	47,717
Other long-term liabilities	41,782	51,517
Shareholders' equity	249,831	325,586
Total liabilities and shareholders' equity	$ 422,295	$ 525,765

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
License and milestone fees	$ 6,973	$ 252	$ 37,865	$ 409
Non-cash royalty revenue	7,116	16,690	13,544	32,235
Research and development support	73	6	831	10
Total revenues	14,162	16,948	52,240	32,654
Expenses:				
Research and development	51,422	34,589	95,704	69,002
Selling, general and administrative	23,793	9,728	40,441	19,937
Total operating expenses	75,215	44,317	136,145	88,939
Loss from operations	(61,053)	(27,369)	(83,905)	(56,285)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(1,078)	(3,557)	(2,327)	(8,201)

Interest expense on convertible bonds	-	(23)	-	(47)
Other income (loss), net	110	208	66	(259)
Net loss	$ (62,021)	$ (30,741)	$ (86,166)	$ (64,792)
Basic and diluted net loss per common share	**$ (0.24)**	**$ (0.15)**	**$ (0.34)**	**$ (0.32)**
Basic and diluted weighted average common shares outstanding	**253,336**	**199,890**	**253,263**	**199,365**

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