ImmunoGen Reports Recent Progress and 2021 Financial Results

February 25, 2022

Positive Top-Line Data from Pivotal SORAYA Trial of Mirvetuximab Soravtansine in Ovarian Cancer; Detailed Results to be Presented in Plenary Session at SGO in March

Mirvetuximab BLA On Track for Submission this Quarter

IMGN632 Triplet Data Demonstrating Manageable Safety Profile and Encouraging Activity in AML Highlighted in Oral Presentation at ASH 2021; Top-Line Data from Pivotal CADENZA Trial of IMGN632 in BPDCN Expected in H2 2022

Appointments of Chief Commercial Officer and Head of Medical Affairs Support Transition to a Fully-Integrated Oncology Company

Ended 2021 with over $475 Million of Cash on the Balance Sheet, Extending Anticipated Cash Runway into 2024

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

WALTHAM, Mass.--(BUSINESS WIRE)--Feb. 25, 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 and year ended December 31, 2021.

“2021 was a productive year for ImmunoGen, highlighted by positive pivotal data for our lead program, advances across our earlier-stage portfolio, and further strengthening our balance sheet and management team,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “The top-line SORAYA data provide the opportunity to establish mirvetuximab soravtansine as the new standard of care for patients with FRα-positive platinum-resistant ovarian cancer, and we look forward to presenting detailed results from SORAYA during the plenary session at SGO next month.”

Enyedy continued, “We also formalized our plans to expand mirvetuximab into platinum-sensitive disease as a monotherapy and in combinations to serve a broader population of ovarian cancer patients, presented promising initial data for IMGN632, now known as pivekimab sunirine, in relapsed/refractory AML and frontline BPDCN at ASH, continued dose-escalation for IMGC936, and submitted the IND for IMGN151. Together with the appointment of key leadership positions and an oversubscribed follow-on offering in the fourth quarter, this progress positions us for success in 2022 and beyond. We have an exciting year ahead, with the potential launch of our first product, top-line data for our second pivotal program, advancement of our earlier-stage portfolio, and further building our pipeline and research capabilities.”

RECENT PROGRESS

- Reported positive top-line data from SORAYA, a pivotal single-arm study of mirvetuximab soravtansine (mirvetuximab) in folate receptor alpha (FRα)-high platinum-resistant ovarian cancer in patients previously treated with Avastin® (bevacizumab).
- Continued patient enrollment in the confirmatory MIRASOL study.
- Initiated accrual in PICCOLO, a single-arm study of mirvetuximab monotherapy in FRα-high recurrent platinum-sensitive ovarian cancer.
- Aligned with the US Food and Drug Administration (FDA) on the design for GLORIOSA, a randomized Phase 3 study of mirvetuximab in combination with bevacizumab maintenance in FRα-high 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.
- Continued the pivotal Phase 2 CADENZA study of pivekimab sunirine (pivekimab, formerly IMGN632) in frontline and relapsed/refractory (R/R) blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- Presented initial data from the Phase 1b/2 study of pivekimab in combination with Vidaza® (azacitidine) and Venclexta® (venetoclax) in R/R acute myeloid leukemia (AML) in an oral session, and initial frontline BPDCN data in a poster session, at the 2021 American Society of Hematology (ASH) Annual Meeting.
- Opened an expansion cohort combining pivekimab, azacitidine, and venetoclax in unfit relapsed AML.
- Advanced dose escalation in the Phase 1 study of IMGC936 in multiple solid tumor types.
- Submitted the investigational new drug (IND) application for IMGN151.
- Appointed Kristen Harrington-Smith as Chief Commercial Officer, Mimi Huizinga, MD, MPH, FACP as Head of Medical Affairs, and Tracey L. McCain, Esq. to the Board of Directors.
- Announced a global licensing agreement granting Eli Lilly and Company (Lilly) exclusive rights to research, develop, and commercialize ADCs directed to targets selected by Lilly based on ImmunoGen’s novel camptothecin technology.

ANTICIPATED UPCOMING EVENTS

- Present full SORAYA data during the plenary session at the Society of Gynecologic Oncology (SGO) Annual Meeting in March.
- Submit the biologics license application (BLA) to the FDA for mirvetuximab in FRα-high platinum-resistant ovarian cancer

in the first quarter of 2022 to support potential accelerated approval and launch.
- Generate top-line data for the confirmatory MIRASOL study in the third quarter of 2022.
- Initiate GLORIOSA, a randomized Phase 3 trial of mirvetuximab in combination with bevacizumab maintenance in FRα-high platinum-sensitive ovarian cancer, in the second quarter of 2022.
- Initiate 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 with platinum-sensitive ovarian cancer, in the second quarter of 2022.
- Report top-line data from the pivotal CADENZA study of pivekimab in BPDCN in the second half of 2022.
- Initiate expansion cohort combining pivekimab, azacitidine, and venetoclax in frontline AML.
- Complete dose-escalation in the Phase 1 study evaluating IMGC936, with initial data anticipated in 2022.
- Begin enrollment in the Phase 1 study of IMGN151 following submission of chemistry, manufacturing, and controls (CMC) information to the FDA.

FINANCIAL RESULTS

Total revenues were $28.0 million for the quarter ended December 31, 2021 compared to $85.8 million for the quarter ended December 31, 2020, and $69.9 million for the year ended December 31, 2021 compared to $132.3 million for the year ended December 31, 2020. The decrease in both periods was driven by the recognition of a $60.5 million upfront fee received under the Company's collaboration agreement with Jazz Pharmaceuticals during the quarter and year ended December 31, 2020 and a reduction in non-cash royalty revenue in 2021 due to the completion of the first tranche of payments under the 2015 Kadcyla® royalties agreement. Partially offsetting these decreases, during the quarter and year ended December 31, 2021, the Company recognized $14.6 million of the $40.0 million upfront fee previously received pursuant to the Company's collaboration agreement with Huadong Medicine.

Research and development expenses rose to $49.0 million for the quarter ended December 31, 2021 compared to $39.6 million for the quarter ended December 31, 2020, and $151.1 million for the year ended December 31, 2021 compared to $114.6 million for the year ended December 31, 2020. The increases in both periods were driven by greater clinical trial expenses, personnel and temporary staffing costs, external manufacturing costs, and third-party service fees in support of commercial readiness.

General and administrative expenses were $13.6 million for the quarter ended December 31, 2021 compared to $9.7 million for the quarter ended December 31, 2020, and $43.8 million for the year ended December 31, 2021 compared to $38.6 million for the year ended December 31, 2020. The increases in both periods were driven by higher professional fees and personnel expenses, including greater non-cash stock compensation expense.

Net loss for the fourth quarter of 2021 was $(37.2) million, or $(0.17) per diluted share, compared to net income of $31.4 million, or $0.16 per diluted share, for the fourth quarter of 2020. Net loss for the year ended December 31, 2021 was $(139.3) million, or $(0.68) per diluted share, compared to a net loss of $(44.4) million, or $(0.25) per diluted share, for the year ended December 31, 2020.

ImmunoGen had $478.8 million in cash and cash equivalents as of December 31, 2021, compared with $293.9 million as of December 31, 2020, and had $2.1 million of convertible debt outstanding as of December 31, 2020. There was no convertible debt outstanding as of December 31, 2021. Cash used in operations was $169.4 million for the year ended December 31, 2021 compared with $78.6 million for the year ended December 31, 2020, with the prior year benefitting from a $40 million upfront license payment received from Huadong Medicine and lower operating expenses for the year as discussed above. Capital expenditures were $(1.4) million for year ended December 31, 2021, compared with $0.5 million of net proceeds from the sale of equipment in the year ended December 31, 2020.

FINANCIAL GUIDANCE

For 2022, ImmunoGen expects:

- 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 yet include 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, dial (877) 621-5803; the conference ID is 5566069. 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.

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 submission of the Company's BLA to the FDA for mirvetuximab, the potential accelerated approval and commercial launch of mirvetuximab, the initiation of Trial 0420, the GLORIOSA Phase 3 trial, the expansion cohort combining pivekimab, azacitidine, and venetoclax in frontline AML, the completion of the dose-escalation Phase 1 study evaluating IMGC936 and the enrollment 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 full SORAYA data, top-line data for the MIRASOL study, top-line data from the CADENZA study, and initial data from the Phase 1 dose-escalation study evaluating IMGNC936; 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 March 1, 2021, 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)

	December 31, 2021	December 31, 2020
ASSETS		
Cash and cash equivalents	$ 478,750	$ 293,856
Other assets	47,015	61,216
Total assets	$ 525,765	$ 355,072
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	$ 44,351	$ 29,249
Other current liabilities	56,594	93,074
Long-term portion of deferred revenue	47,717	80,860
Other long-term liabilities	51,517	62,319
Shareholders' equity	325,586	89,570
Total liabilities and shareholders' equity	$ 525,765	$ 355,072

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenues:				
License and milestone fees	$ 19,564	$ 62,417	$ 22,650	$ 63,742
Non-cash royalty revenue	8,040	23,370	46,808	68,529
Research and development support	388	11	398	28
Total revenues	27,992	85,798	69,856	132,299
Expenses:				
Research and development	48,968	39,578	151,117	114,592
General and administrative	13,578	9,738	43,812	38,600

Restructuring charge	-	(37)	-	1,487
Total operating expenses	62,546	49,279	194,929	154,679
(Loss) income from operations	(34,554)	36,519	(125,073)	(22,380)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(2,151)	(5,679)	(13,103)	(23,107)
Interest expense on convertible bonds	-	(24)	(47)	(95)
Other (loss) income, net	(467)	572	(1,080)	1,210
Net (loss) income	$ (37,172)	$ 31,388	$ (139,303)	$ (44,372)
Net (loss) income per common share - basic	**$ (0.17)**	**$ 0.17**	**$ (0.68)**	**$ (0.25)**
Net (loss) income per common share - diluted	**$ (0.17)**	**$ 0.16**	**$ (0.68)**	**$ (0.25)**
Shares used in computation of per share amounts - basic	**215,830**	**188,681**	**206,147**	**176,153**
Shares used in computation of per share amounts - diluted	**215,830**	**191,089**	**206,147**	**176,153**

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