ImmunoGen Reports Recent Progress and 2022 Financial Results

March 1, 2023

Launched ELAHERE™ (mirvetuximab soravtansine-gynx), the First and Only ADC Approved for Platinum-Resistant Ovarian Cancer in the US; ELAHERE Monotherapy and in Combination with Bevacizumab Included in NCCN Guidelines and Compendium

Top-Line Results from Confirmatory MIRASOL Trial Anticipated in Q2 2023; Expected to Support Full Approval of ELAHERE in the US and Expansion into Europe

Encouraging Safety and Efficacy Data from Pivekimab Sunirine Triplet in AML Presented in Oral Session at ASH 2022; Clinical Collaboration with Gilead Announced to Evaluate Pivekimab with Magrolimab in Relapsed/Refractory AML

Announced a Global, Multi-Target License and Option Agreement of ImmunoGen's ADC Technology to Vertex; ImmunoGen to Receive a $15 Million Upfront Payment and is Eligible to Receive Up to $337 Million in Potential Option Fees and Milestone Payments Plus Tiered Royalties on a Per Target Basis

Appointments of Michael Vasconcelles as Executive Vice President, Research, Development, and Medical Affairs, and Daniel Char as Chief Legal Officer, Further Strengthen Management Team

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

WALTHAM, Mass.--(BUSINESS WIRE)--Mar. 1, 2023-- 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, 2022.

“We significantly advanced the business on multiple fronts over the last 12 months, most notably with the accelerated approval and launch of ELAHERE for patients with platinum-resistant ovarian cancer,” said Mark Enyedy, ImmunoGen’s President and Chief Executive Officer. “We have seen broad and deep adoption of ELAHERE to date, with FRα testing, managed care coverage, and provider access all exceeding our expectations. Building upon this progress and in line with our goal of obtaining full approval for ELAHERE in the US and expanding into Europe, we will imminently reach the requisite number of PFS events in the confirmatory MIRASOL trial and expect to announce top-line data in the second quarter. In parallel, we are pursuing our broader development program in support of moving ELAHERE into platinum-sensitive disease and positioning ELAHERE as the combination agent of choice in ovarian cancer.”

Enyedy continued, “Turning to our second pivotal program, pivekimab sunirine, we presented promising findings from our triplet expansion cohorts in AML in an oral presentation at ASH in December, and continued enrollment in the pivotal CADENZA trial in frontline BPDCN with top-line data in de novo patients anticipated in 2024. We are also progressing our earlier-stage portfolio with the completion of dose escalation in the Phase 1 study of IMGC936, while also having dosed the first patient in our Phase 1 trial for IMGN151 in January. Combining our commitment to advance our pipeline of novel ADCs along with driving the commercial uptake of ELAHERE in the US, we are well positioned for another exciting and productive year.”

RECENT PROGRESS

ELAHERE (mirvetuximab soravtansine-gynx)

- Received US Food and Drug Administration (FDA) accelerated approval of ELAHERE for folate receptor alpha (FRα)-positive platinum-resistant ovarian cancer (PROC) on November 14, 2022.
- Generated $2.6 million in net sales for the fourth quarter of 2022.
- ELAHERE monotherapy and in combination with bevacizumab included in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines and compendium.

Clinical Pipeline

- Published manuscript on the safety and efficacy of mirvetuximab in PROC in the SORAYA trial in the *Journal of Clinical Oncology*.
- Published manuscript on the safety and efficacy of mirvetuximab in combination with bevacizumab in PROC in *Gynecologic Oncology*.
- Completed enrollment in PICCOLO, a single-arm study of mirvetuximab monotherapy in FRα-high recurrent platinum-sensitive ovarian cancer (PSOC).
- Presented data from expansion cohorts in the Phase 1b/2 study evaluating the pivekimab sunirine (pivekimab) triplet with Vidaza® (azacitidine) and Venclexta® (venetoclax) in relapsed/refractory (R/R) and initial data in frontline unfit acute myeloid leukemia (AML) in an oral presentation at the 2022 American Society of Hematology (ASH) Annual Meeting in December.
- Progressed the pivotal Phase 2 CADENZA study of pivekimab sunirine (pivekimab) in frontline and relapsed/refractory (R/R) blastic plasmacytoid dendritic cell neoplasm (BPDCN).
- Completed dose escalation in the Phase 1 study of IMGC936 in multiple solid tumor types and initiated expansion cohorts

in triple-negative breast cancer (TNBC) and non-small cell lung cancer (NSCLC).
- Enrolled the first patient in the Phase 1 study of IMGN151 in January 2023.

Corporate Development

- Announced a global, multi-target license and option agreement granting Vertex Pharmaceuticals rights to conduct research using ImmunoGen's ADC technology to discover novel targeted conditioning agents for use with gene editing in exchange for a $15 million upfront payment and up to $337 million in potential option exercise fees, development and commercial milestones, and tiered royalties on a per target basis.
- Announced a clinical collaboration with Gilead to evaluate the safety and anti-leukemia activity of pivekimab in combination with magrolimab, a potential first-in-class CD47 inhibitor, in patients with R/R CD123-positive AML.
- Appointed Michael Vasconcelles, MD, as Executive Vice President, Research, Development, and Medical Affairs, and Daniel Char, JD, as Senior Vice President and Chief Legal Officer.

ANTICIPATED UPCOMING EVENTS

- Report top-line data for MIRASOL in the second quarter of 2023.
- Submit the Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for ELAHERE in FRα-high PROC in the second half of 2023 to support potential approval and launch.
- Submit the supplemental Biologics License Application (sBLA) to the FDA in the second half of 2023 to support the conversion of the accelerated approval of ELAHERE to a full approval.
- Our partner, Huadong Medicine, to submit the biologics license application (BLA) to the National Medical Products Administration (NMPA) of China for ELAHERE in FRα-high PROC in the second half of 2023 to support potential approval and launch.
- Present efficacy data from the SORAYA trial by sequence of treatment and final overall survival analysis at the Society of Gynecologic Oncology (SGO) 2023 Annual Meeting in March.
- Report on the primary endpoint for PICCOLO before the end of 2023.
- Complete enrollment of the efficacy evaluable cohort of *de novo* BPDCN patients in the pivotal phase 2 CADENZA study by the end of 2023.
- Initiate the combination cohort of pivekimab with magrolimab in R/R AML in collaboration with Gilead in the second half of 2023.
- Report dose escalation data in Phase 1 trial of IMGC936 and initial experience in expansion cohorts in the second quarter of 2023.

FINANCIAL RESULTS

Total revenues were $41.2 million for the quarter ended December 31, 2022 compared to $28.0 million for the quarter ended December 31, 2021, and $108.8 million for the year ended December 31, 2022 compared to $69.9 million for the year ended December 31, 2021. The increase in the quarter ended December 31, 2022 was primarily driven by one-time milestone payments achieved pursuant to the Company's license and collaboration agreements with Huadong Medicine and Viridian Therapeutics. In addition to greater partner milestones achieved, the increase for the current year was driven by one-time license fees received pursuant to agreements executed with Eli Lilly and Magenta Therapeutics in 2022, as well as greater amortization in 2022 of the $40.0 million upfront fee previously received pursuant to the Company's collaboration agreement with Huadong Medicine. The Company also recorded $2.6 million in net product revenue from sales of ELAHERE for the quarter and year ended December 31, 2022.

Research and development expenses rose to $58.5 million for the quarter ended December 31, 2022 compared to $49.0 million for the quarter ended December 31, 2021, and $213.4 million for the year ended December 31, 2022 compared to $151.1 million for the year ended December 31, 2021. The increases in both periods were driven by greater personnel and temporary staffing costs, external manufacturing costs, and third-party service fees, including medical affairs' activities in support of the US commercial launch of ELAHERE in the fourth quarter of 2022, as well as greater clinical trial expenses. Additionally, research and development expenses for the year ended December 31, 2022 included $8.9 million of research costs to expand our ADC pipeline, inclusive of a one-time $7.5 million upfront fee paid to Oxford BioTherapeutics.

Selling, general and administrative expenses were $42.1 million for the quarter ended December 31, 2022 compared to $13.6 million for the quarter ended December 31, 2021, and $116.1 million for the year ended December 31, 2022 compared to $43.8 million for the year ended December 31, 2021. The increases in both periods were due primarily to building our commercial infrastructure and capabilities, including personnel-related costs and sales and marketing activities in support of the US launch of ELAHERE in the fourth quarter of 2022.

Net loss for the fourth quarter of 2022 was $59.0 million, or $0.23 per diluted share, compared to net loss of $37.2 million, or $0.17 per diluted share, for the fourth quarter of 2021. Net loss for the year ended December 31, 2022 was $222.9 million, or $0.88 per diluted share, compared to a net loss of $139.3 million, or $0.68 per diluted share, for the year ended December 31, 2021.

ImmunoGen had $275.1 million in cash and cash equivalents as of December 31, 2022, compared with $478.8 million as of December 31, 2021. Cash used in operations was $229.8 million for the year ended December 31, 2022 compared with $169.4 million for the year ended December 31, 2021. Capital expenditures were $1.4 million in each of the years ended December 31, 2022 and 2021.

During the quarter ended December 31, 2022, the Company sold 5.2 million shares of its common stock through its At-the-Market facility, generating net proceeds to the Company of $25.6 million.

FINANCIAL GUIDANCE

For 2023, ImmunoGen expects:

- revenues, excluding product revenue from ELAHERE, between $30 million and $35 million; and
- operating expenses between $310 million and $320 million.

ImmunoGen expects to provide ELAHERE product revenue guidance later this year.

Excluding anticipated ELAHERE and collaboration revenue, our level of cash and cash equivalents as of December 31, 2022, alone is not sufficient to meet our current operating plans through March 1, 2024. With the addition of forecasted ELAHERE product revenue and milestone payments under existing collaboration agreements, we expect these amounts combined with existing cash and cash equivalents will fund operations for more than 12 months from the date of this release. The Company intends to raise additional funds through equity, debt, or other financings.

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 ELAHERE™ (MIRVETUXIMAB SORAVTANSINE-GYNX)
ELAHERE (mirvetuximab soravtansine-gynx) is a first-in-class ADC comprising a folate receptor alpha-binding antibody, cleavable linker, and the maytansinoid payload DM4, a potent tubulin inhibitor designed to kill the targeted cancer cells.

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Eye problems are common with ELAHERE and can be severe. ELAHERE also can cause severe or life-threatening inflammation of the lungs that may lead to death and patients may develop nerve problems called peripheral neuropathy during treatment. Please see full Prescribing Information, including Boxed Warning, and Medication Guide for ELAHERE.

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. ELAHERE™ is a trademark of ImmunoGen, Inc.

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 2023; the Company's anticipated cash runway; the Company's expectations regarding future financing activities; 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 commercialization of ELAHERE, the potential of ELAHERE to become the combination agent of choice, and the potential full approval of ELAHERE in the US and expansion to Europe; the timing and presentation of preclinical and clinical data on the Company's product candidates, including data from the MIRASOL trial, data from the CADENZA trial, data from the SORAYA trial, and data from the Phase 1 trial of 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 ELAHERE 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; 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 ELAHERE in light of the FDA granting 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, 2023 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, 2022	December 31, 2021
ASSETS		

Cash and cash equivalents	$ 275,138	$ 478,750
Other assets	73,798	47,015
Total assets	$ 348,936	$ 525,765
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current portion of deferred revenue	$ 13,856	$ 44,351
Other current liabilities	108,002	56,594
Long-term portion of deferred revenue	36,355	47,717
Other long-term liabilities	34,897	51,517
Shareholders' equity	155,826	325,586
Total liabilities and shareholders' equity	$ 348,936	$ 525,765

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
Revenues:				
License and milestone fees	$ 30,780	$ 19,564	$ 76,027	$ 22,650
Non-cash royalty revenue	7,724	8,040	29,261	46,808
Product revenue, net	2,554	-	2,554	-
Research and development support	109	388	940	398
Total revenues	41,167	27,992	108,782	69,856
Cost and operating expenses:				
Cost of sales	176	-	176	-
Research and development	58,485	48,968	213,370	151,117
Selling, general and administrative	42,065	13,578	116,129	43,812
Total cost and operating expenses	100,726	62,546	329,675	194,929
Loss from operations	(59,559)	(34,554)	(220,893)	(125,073)
Non-cash interest expense on liability related to sale of future royalty & convertible bonds	(971)	(2,151)	(4,165)	(13,103)
Interest expense on convertible bonds	-	-	-	(47)
Other income (loss), net	2,740	(467)	3,347	(1,080)
Loss before income taxes	$ (57,790)	$ (37,172)	$ (221,711)	$ (139,303)
Income tax expense	1,218	-	1,218	-
Net loss	$ (59,008)	$ (37,172)	$ (222,929)	$ (139,303)
Basic and diluted net loss per common share	**$ (0.23)**	**$ (0.17)**	**$ (0.88)**	**$ (0.68)**
Basic and diluted weighted average common shares outstanding	**254,405**	**215,830**	**253,361**	**206,147**

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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.