IGM Biosciences Announces Third Quarter 2023 Financial Results

November 13, 2023

– Third IND cleared for imvotamab in autoimmune diseases –

– International sites opened for aplitabart randomized clinical trial –

MOUNTAIN VIEW, Calif., Nov. 13, 2023 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies, today announced its financial results for the quarter ended September 30, 2023.

"During the third quarter, we continued to execute across our clinical development pipeline," said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. "We have significantly expanded the number of active sites for our aplitabart randomized study, including multiple international sites, begun our Phase 1b clinical trials of imvotamab in severe systemic lupus erythematosus and severe rheumatoid arthritis and received FDA clearance of our IND application to begin a third Phase 1b autoimmune clinical trial of imvotamab. Our progress in the clinical development of these pipeline product candidates reinforces our commitment to the broad development of our Death Receptor 5 agonist platform and our T cell engager platform for autoimmune diseases."

Pipeline Progress

Aplitabart (DR5 agonist)

- **Clinical development of aplitabart advances.**
  - **Enrollment ongoing in the randomized colorectal cancer clinical trial.** The Company continues to enroll patients in a randomized clinical trial of aplitabart, a Death Receptor 5 agonist, plus FOLFIRI and bevacizumab in second-line metastatic colorectal cancer, with a goal of enrolling approximately 110 patients by the end of the first quarter of 2024. In addition to clinical sites in the United States, this study will include multiple sites in Asia and Europe. This randomized trial is designed to assess the additional benefit of 3 mg/kg of aplitabart to the current standard of care treatment arm of FOLFIRI and bevacizumab, with a primary endpoint of progression-free survival and secondary endpoints of overall response rate and overall survival.
  - **Dosing at 10 mg/kg ongoing in the single arm colorectal cancer clinical trial.** The Company continues to treat later line colorectal cancer patients in its single arm combination clinical trial of 10 mg/kg of aplitabart and FOLFIRI. The Company expects to complete enrollment of patients in this 10 mg/kg single arm combination study in the first half of 2024.
  - **Ongoing venetoclax combination.** The Company continues to treat patients in its initial Phase 1 single arm study of aplitabart in acute myeloid leukemia in combination with venetoclax and azacytidine.
  - **Ongoing birinapant combination.** The Company continues to treat patients in its aplitabart plus birinapant Phase 1 combination cohort.

Imvotamab (CD20 x CD3)

- **Two autoimmune clinical trials ongoing.** Following the clearance of the Company's two Investigational New Drug (IND) applications with the U.S. Food and Drug Administration (FDA) for imvotamab, an IgM-based CD20 x CD3 bispecific antibody T cell engager, the Company has begun two Phase 1b clinical trials, one in severe systemic lupus erythematosus (SLE) and one in severe rheumatoid arthritis (RA).
- **FDA clearance to begin third autoimmune clinical trial.** In the third quarter, the Company received clearance from the FDA of its IND application for the use of imvotamab in treating idiopathic inflammatory myopathies (myositis).
- **Imvotamab preclinical data**. In November 2023, the Company presented preclinical data for imvotamab at the American College of Rheumatology Annual Meeting. The results were featured in a poster presentation titled "Therapeutic Potential of Imvotamab, a CD20-Targeted Bispecific IgM T Cell Engager, for the Treatment of Refractory Autoimmune Disease Patients", which highlighted the ability of imvotamab to effectively deplete CD20+ B cells in tissue as well as to deplete low expressing CD20+ cells. These preclinical results support the advancement of imvotamab into Phase 1b clinical trials in autoimmune disease and may indicate differentiated activity as compared to anti-CD20 IgG1 antibodies.

IGM-7354 (IL-15 x PD-L1)

- **Phase 1 trial continues.** The Company continues to treat patients in a Phase 1 clinical trial exploring the safety, efficacy,

and biomarker activity of IGM-7354, an IgM-targeted immunostimulatory IL-15 cytokine, in the treatment of patients with solid tumors.

IGM-2644 (CD38 x CD3)

- **Phase 1 trial continues.** The Company continues to treat patients in a Phase 1 clinical trial exploring the safety and efficacy of IGM-2644, a CD38 x CD3 IgM T cell engaging antibody, in patients with recurrent or refractory multiple myeloma.

Third Quarter 2023 Financial Results

- **Cash and Investments:** Cash and investments as of September 30, 2023 were $387.0 million, compared to $427.2 million as of December 31, 2022.
- **Collaboration Revenue:** For the third quarter of 2023, collaboration revenues were $0.5 million, compared to $0.3 million for the same period in 2022.
- **Research and Development (R&D) Expenses:** For the third quarter of 2023, R&D expenses were $54.8 million, compared to $48.2 million for the same period in 2022.
- **General and Administrative (G&A) Expenses:** For the third quarter of 2023, G&A expenses were $12.5 million, compared to $12.7 million for the same period in 2022.
- **Net Loss:** For the third quarter of 2023, net loss was $62.0 million, or a loss of $1.04 per share, compared to a net loss of $58.0 million, or a loss of $1.32 per share, for the same period in 2022.

2023 Financial Guidance

The Company expects full year 2023 GAAP operating expenses of $275 million to $285 million, including estimated non-cash stock-based compensation expense of approximately $50 million, and full year collaboration revenue of approximately $2 million related to the Sanofi agreement. The Company expects to end 2023 with more than $325 million in cash and investments, and the Company expects its existing cash and investments and anticipated collaboration payments to fund operations into the second half of 2025.

About IGM Biosciences, Inc.

IGM Biosciences is a clinical-stage biotechnology company committed to developing and delivering a new class of medicines to treat patients with cancer, autoimmune and inflammatory diseases and infectious diseases. IGM's pipeline of clinical and preclinical assets is based on the IgM antibody, which has 10 binding sites compared to conventional IgG antibodies with only 2 binding sites. IGM also has an exclusive worldwide collaboration agreement with Sanofi to create, develop, manufacture, and commercialize IgM antibody agonists against oncology and immunology and inflammation targets. For more information, please visit www.igmbio.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements. Such forward-looking statements are not based on historical fact and include, but are not limited to: the potential of, and expectations regarding, IGM's technology platform and its IgM antibodies and product candidates, including aplitabart, imvotamab, IGM-7354 and IGM-2644; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of aplitabart, imvotamab, IGM-7354 and IGM-2644, including patient enrollment; IGM's expectations regarding its financial position and guidance, including collaboration revenue, operating expenses, stock-based compensation expense, ending 2023 cash and investments and projected cash runway; and statements by IGM's Chief Executive Officer. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially, including but not limited to: IGM's early stages of clinical drug development; risks related to the use of engineered IgM antibodies, which is a novel and unproven therapeutic approach; IGM's ability to demonstrate the safety and efficacy of its product candidates; IGM's ability to successfully and timely advance its product candidates through clinical trials; IGM's ability to enroll patients in its clinical trials; the potential for the results of clinical trials to differ from preclinical, preliminary, initial or expected results; the risk of significant adverse events, toxicities or other undesirable side effects; IGM's ability to successfully manufacture and supply its product candidates for clinical trials; the potential impact of continuing or worsening supply chain constraints; the risk that all necessary regulatory approvals cannot be obtained; the potential market for IGM's product candidates, and the progress and success of alternative therapeutics currently available or in development; IGM's ability to obtain additional capital to finance its operations; uncertainties related to the projections of the size of patient populations suffering from the diseases IGM is targeting; IGM's ability to obtain, maintain and protect its intellectual property rights; developments relating to IGM's competitors and its industry, including competing product candidates and therapies; any potential delays or disruptions resulting from catastrophic events, including epidemics or other outbreaks of infectious disease; general economic and market conditions, including inflation; and other risks and uncertainties, including those more fully described in IGM's filings with the Securities and Exchange Commission (SEC), including IGM's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2023 and in IGM's future reports to be filed with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and IGM specifically disclaims any obligation to update any forward-looking statement, except as required by law.

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Selected Statement of Operations Data
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 509	$ 331	$ 1,479	$ 697
Operating expenses:				
Research and development [1]	54,762	48,179	161,329	134,272
General and administrative [1]	12,507	12,664	38,492	38,117
Total operating expenses	67,269	60,843	199,821	172,389
Loss from operations	(66,760)	(60,512)	(198,342)	(171,692)
Other income (expense)				
Interest income	5,011	2,475	13,077	3,289
Other expense	—	—	(20)	(123)
Total other income (expense)	5,011	2,475	13,057	3,166
Loss before income tax expense	(61,749)	(58,037)	(185,285)	(168,526)
Income tax expense	(240)	—	(436)	—
Net Loss	$ (61,989)	$ (58,037)	$ (185,721)	$ (168,526)
Net loss per share, basic and diluted	$ (1.04)	$ (1.32)	$ (3.73)	$ (4.15)
Weighted-average common shares outstanding, basic and diluted	59,580,402	44,034,652	49,778,716	40,634,893
[1] Amounts include stock-based compensation expense as follows:				
Research and development	$ 7,391	$ 6,096	$ 22,078	$ 19,038
General and administrative	4,563	4,720	15,232	14,563
Total stock-based compensation expense	$ 11,954	$ 10,816	$ 37,310	$ 33,601

IGM Biosciences, Inc.
Selected Balance Sheet Data
(unaudited)
(in thousands)

	September 30, 2023	December 31, 2022
Cash and investments	$ 386,991	$ 427,162
Total assets	474,350	513,499
Accounts payable	3,913	2,512
Accrued liabilities	27,933	33,621
Deferred revenue	147,452	148,931
Total liabilities	220,488	226,236
Accumulated deficit	(760,547)	(574,826)
Total stockholders' equity	253,862	287,263

Source: IGM Biosciences, Inc.