IGM Biosciences Announces Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

March 30, 2023

– Encouraging initial data from IGM-8444 combination with FOLFIRI; first patient dosed in randomized trial –

– Imvotamab to move forward into clinical studies in multiple autoimmune diseases –

– Initiation of Phase 1 clinical trial for targeted immunostimulatory IL-15 cytokine IGM-7354 in patients with solid tumors –

– Company to hold conference call and webcast today at 4:30 p.m. EDT –

MOUNTAIN VIEW, Calif., March 30, 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 fourth quarter and full year ended December 31, 2022 and provided an update on recent developments.

“During 2022 we continued to extend the application of our IgM antibody platform by preparing imvotamab for clinical trials in autoimmune diseases and signing an exclusive worldwide collaboration agreement with Sanofi to develop novel IgM agonist antibodies for oncology and autoimmune diseases,” said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. “Also, and perhaps most significantly, the initial clinical results from IGM-8444, our anti-death receptor 5 IgM antibody, highlight the exciting potential of IgM antibodies as agonist antibody medicines. We are announcing today that we have dosed the first patient in our randomized clinical trial of IGM-8444 in combination with standard of care FOLFIRI chemotherapy and bevacizumab in second line metastatic colorectal cancer patients. We are also pleased with the expanded safety and efficacy data for imvotamab at 100 mg that we have developed through our non-Hodgkin's lymphoma clinical trials, and we believe that imvotamab’s encouraging safety profile may be an important differentiating factor in the exciting new field of T cell engagers in autoimmune disease.”

Mr. Schwarzer continued, “We expect that 2023 will also be an important year for the expansion and validation of IGM’s platform. Already this year, we have treated the first patients in our initial clinical study of IGM-7354, an IgM targeted immunostimulatory IL-15 cytokine, which could be used for the treatment of patients with solid and hematologic malignancies, potentially in combination with cellular therapies, such as CAR-T and CAR-NK cells. We are also initiating clinical studies of IGM-2644, our CD38 x CD3 T cell engaging IgM antibody, which we hope will prove to be a safe and more potent form of anti-CD38 therapy for multiple myeloma, including for patients who have previously been treated with daratumumab. We also plan to file Investigational New Drug applications and initiate clinical studies for imvotamab in multiple autoimmune diseases this year, beginning with systemic lupus erythematosus and rheumatoid arthritis.”

Pipeline Updates

IGM-8444 (DR5)

- **First patient dosed in randomized colorectal cancer clinical trial.** The Company announced today that it has treated the first patient in a randomized clinical trial of IGM-8444, an IgM agonist antibody targeting death receptor 5 (DR5), plus FOLFIRI and bevacizumab in second line metastatic colorectal cancer. The study is designed to assess the benefit of IGM-8444 when combined with the current standard of care regimen of FOLFIRI and bevacizumab. The Company will be assessing both the 3 mg/kg and 10 mg/kg dose levels of IGM-8444 with a primary endpoint of progression free survival and secondary endpoints of overall response rate and overall survival as compared to the current standard of care treatment arm.
- **Encouraging data in combination with FOLFIRI.** As announced in January 2023, IGM-8444 showed an encouraging safety profile which was broadly comparable to that expected from chemotherapy alone in this setting. Specifically, no signs of drug related clinically significant hepatotoxicity were observed, as only Grade 1 and Grade 2 transient drug related liver enzyme elevations were seen. In patients with metastatic colorectal cancer, the combination of IGM-8444 and FOLFIRI showed promising activity at 3 mg/kg, with multiple confirmed responses observed, including some in patients who had previously progressed on FOLFIRI.
- **Clinical biomarker data supports activity and dose response across multiple dose levels.** Clinical biomarker data from 64 patients treated in monotherapy and combination dose cohorts across multiple dose levels of IGM-8444 in the Company’s ongoing Phase 1 clinical trial showed that virtually all of these patients (60 of 64) showed an increase in levels of the cell death biomarker caspase-3 following treatment with IGM-8444. This increase began to be seen after the initial dose of IGM-8444 and showed a trend towards a dose dependent increase between the two highest dose levels tested of 3 mg/kg and 10 mg/kg.
- **First patient dosed in venetoclax combination.** The Company also announced today that it has dosed the first patient in

its IGM-8444 plus venetoclax and azacytidine Phase 1 combination cohort in subjects with acute myeloid leukemia.
- **Dosing ongoing in the fifth birinapant dose cohort.** The Company further announced today that it is currently treating patients in its fifth birinapant Phase 1 combination dose escalation cohort. To date, there have not been any observed dose limiting toxicities in combination with birinapant.

Imvotamab (CD20 x CD3)

- **Advancing into multiple autoimmune clinical trials.** The Company announced today that it plans to file Investigational New Drug (IND) applications in the second quarter of 2023 this year to begin clinical testing of imvotamab in severe systemic lupus erythematosus and severe rheumatoid arthritis. The Company believes that the clinical safety and efficacy profile of imvotamab positions it very well for the exciting new area of treating autoimmune disease with T cell engagers.
- **Cytokine release incidence of less than 10% at 100 mg dose level.** The Company announced today that as of its most recent data assessment the incidence of cytokine release syndrome was nine percent (9%) combined over all safety evaluable patients treated with the 100 mg titration weekly dosing regimen in its Phase 1 and Phase 2 non-Hodgkin's lymphoma (NHL) studies.
- **DLBCL complete response rate greater than 30% at 100 mg dose level.** The Company also announced today that, although the patient numbers are very small and additional patients currently on treatment may respond, as of its most recent data assessment it has achieved a complete response rate of greater than 30% combined over all efficacy evaluable diffuse large B cell lymphoma patients treated with the 100 mg titration weekly dosing regimen in its Phase 1 and Phase 2 NHL studies.
- **Redirecting clinical development efforts to autoimmune disease.** In light of its plans for the extensive clinical development of imvotamab in autoimmune diseases and the limited commercial opportunities in monotherapy treatment of NHL, the Company announced today that it has decided to cease further monotherapy clinical development efforts for imvotamab in NHL. The Company continues to believe that the safety and efficacy profile of imvotamab positions it well as a combination partner for the treatment of NHL, and it plans to focus its future efforts in NHL on evaluating combination opportunities and partnerships for imvotamab.

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

- **Phase 1 trial initiated.** As previously announced, the Company has initiated a 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.
- **First two patients dosed.** The Company announced today that it has successfully dosed two patients in its clinical trial of IGM-7354 without any drug related safety issues to date.
- **Preclinical data presented.** In November 2022, the Company presented preclinical results at the Society for Immunotherapy of Cancer Annual Meeting. The data was featured in a poster titled "IGM-7354, an anti-PD-L1/IL-15 IgM immunocytokine, activates and expands NK cells and effector memory CD8+ T cells in vivo".

IGM-2644 (CD38 x CD3)

- **IND clearance.** The Company announced today that the U.S. Food and Drug Administration has cleared its IND application for a Phase 1 dose escalation trial of IGM-2644, a CD38 x CD3 IgM T cell engaging antibody, in patients with recurrent or refractory multiple myeloma. This study will investigate the initial safety and efficacy of IGM-2644 in patients who have progressed on previous therapies. The Company's ultimate clinical development goal is to establish IGM-2644 as a safe and more potent anti-CD38 therapy, particularly for patients who have received prior daratumumab treatment.
- **Preclinical data.** In December 2022, the Company presented preclinical data for IGM-2644 at the ASH Annual Meeting and Exposition. The results were featured in a poster presentation titled "IGM-2644, a Novel CD38 x CD3 Bispecific IgM T Cell Engager Demonstrates Potent Efficacy on Myeloma Cells with an Improved Preclinical Safety Profile", which highlighted IGM-2644's greater complement dependent cytotoxicity activity as compared to conventional IgG anti-CD38 antibodies. Additionally, IGM-2644 achieved potent T cell dependent cellular cytotoxicity (TDCC) killing of daratumumab-resistant cell lines with minimal cytokine release and potent TDCC killing of myeloma patient samples.

Fourth Quarter and Full Year 2022 Financial Results

- **Cash and Investments:** Cash and investments as of December 31, 2022 were $427.2 million, compared to $229.5 million as of December 31, 2021.
- **Collaboration Revenue:** For the fourth quarter and year ended 2022, collaboration revenues were $0.4 million and $1.1 million, respectively, compared to no revenue for the same period in 2021.
- **Research and Development (R&D) Expenses:** For the fourth quarter and year ended 2022, R&D expenses were $45.0 million and $179.3 million, respectively, compared to $39.2 million and $127.0 million for the fourth quarter and year ended 2021, respectively.
- **General and Administrative (G&A) Expenses:** For the fourth quarter and year ended 2022, G&A expenses were $11.6

million and $49.7 million, respectively, compared to $11.5 million and $38.3 million for the fourth quarter and year ended 2021, respectively.

- **Net Loss:** For the fourth quarter of 2022, net loss was $52.6 million, or a loss of $1.19 per share, compared to a net loss of $50.6 million, or a loss of $1.50 per share, for the fourth quarter of 2021. For the year ended 2022, net loss was $221.1 million, or a loss of $5.32 per share, compared to a net loss of $165.2 million, or a loss of $4.93 per share, for the year ended 2021.

2023 Financial Guidance
The Company expects full year 2023 GAAP operating expenses of $290 million to $300 million, including estimated non-cash stock-based compensation expense of approximately $50 million, and full year collaboration revenue of approximately $3 million related to the Sanofi agreement. The Company expects to end 2023 with a balance of approximately $200 million in cash and investments, and for the balance to enable it to fund its operating expenses and capital expenditure requirements into the second half of 2024.

Conference Call and Webcast
IGM will host a live conference call and webcast at 4:30 p.m. EDT today, March 30, 2023, to discuss the Company's financial results and provide a corporate update. The webcast can be accessed by clicking the link: https://edge.media-server.com/mmc/p/ud83kix8 and will also be available on the "Events and Presentations" page in the "Investors" section of the Company's website.

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. The Company'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. The Company 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, including statements relating to IGM's plans, expectations and forecasts and to future events. Such forward-looking statements include, but are not limited to: the potential of, and expectations regarding, IGM's technology platform and its IgM antibodies and product candidates, including imvotamab, IGM-8444, IGM-7354 and IGM-2644; expectations regarding IGM's collaboration with Sanofi, including the potential benefits and results of such collaboration and the objectives of such collaboration and any future collaborations; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of imvotamab, IGM-8444, IGM-7354 and IGM-2644, including the timing of filing INDs, initiation of clinical trials and 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 preclinical studies and 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; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of collaborations with third parties, including the agreement with Sanofi; 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, if needed; 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 Annual Report on Form 10-K filed with the SEC on March 30, 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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IGM Biosciences, Inc.
Selected Statement of Operations Data
(in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Collaboration revenue	$ 372	$ —	$ 1,069	$ —
Operating expenses:				
Research and development [1]	45,018	39,169	179,289	127,026

General and administrative [1]	11,618	11,511	49,736	38,297
Total operating expenses	56,636	50,680	229,025	165,323
Loss from operations	(56,264)	(50,680)	(227,956)	(165,323)
Other income (expense)				
Interest income	3,746	38	7,035	159
Other expense	(58)	—	(181)	—
Total other income (expense)	3,688	38	6,854	159
Net Loss	$ (52,576)	$ (50,642)	$ (221,102)	$ (165,164)
Net loss per share, basic and diluted	$ (1.19)	$ (1.50)	$ (5.32)	$ (4.93)
Weighted-average common shares outstanding, basic and diluted	44,241,491	33,775,358	41,543,954	33,479,782

[1] Amounts include stock-based compensation expense as follows:

Research and development	$ 6,582	$ 4,659	$ 25,620	$ 12,264
General and administrative	4,527	3,889	19,090	13,609
Total stock-based compensation expense	$ 11,109	$ 8,548	$ 44,710	$ 25,873

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

	December 31,	
	2022	**2021**
Cash and investments	$ 427,162	$ 229,542
Total assets	513,499	298,127
Accounts payable	2,512	5,584
Accrued liabilities	33,621	18,876
Deferred revenue	148,931	—
Total liabilities	226,236	53,219
Accumulated deficit	(574,826)	(353,724)
Total stockholders' equity	287,263	244,908

Source: IGM Biosciences, Inc.