IGM Biosciences Announces First Quarter 2023 Financial Results and Provides Corporate Update

May 12, 2023

– Randomized clinical trial of IGM-8444 plus FOLFIRI and bevacizumab in second line metastatic colorectal cancer underway –

– Plans to present additional non-randomized clinical data for 3 mg/kg of IGM-8444 plus FOLFIRI, with and without bevacizumab, in the middle of 2023 –

– Plans to begin clinical testing of imvotamab in severe systemic lupus erythematosus and severe rheumatoid arthritis –

MOUNTAIN VIEW, Calif., May 12, 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 first quarter ended March 31, 2023 and provided an update on recent developments.

"We are pleased to be underway 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, and we look forward to presenting additional clinical data in the middle of 2023 from our non-randomized Phase 1 clinical study of 3 mg/kg of IGM-8444 plus FOLFIRI, with and without bevacizumab," said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. "We are also looking forward to the start of clinical testing of imvotamab in autoimmune diseases, where we believe the clinical safety and efficacy profile of imvotamab positions us very well for the exciting new area of treating autoimmune disease with T cell engagers."

Pipeline Updates

IGM-8444 (DR5)

- **Clinical development of IGM-8444 advances.** The Company continues to advance the clinical development of IGM-8444, the Company's IgM agonist antibody targeting death receptor 5 (DR5).
  - **Dosing ongoing in the randomized colorectal cancer clinical trial.** The Company is currently treating patients in a randomized clinical trial of IGM-8444 plus FOLFIRI and bevacizumab in second line metastatic colorectal cancer. The Company plans to assess 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.
  - **Dosing ongoing in the venetoclax combination.** The Company is currently treating patients with acute myeloid leukemia in its IGM-8444 plus venetoclax and azacytidine Phase 1 combination cohort.
  - **Dosing ongoing in the fifth birinapant dose cohort.** The Company is also currently treating patients in its fifth birinapant Phase 1 combination dose escalation cohort.
  - **Additional clinical data expected in middle of 2023.** The Company plans to present additional clinical data from the 3 mg/kg of IGM-8444 plus FOLFIRI cohort, with and without bevacizumab, of its non-randomized Phase 1 clinical trial in the middle of 2023.
- **Presented preclinical data.** In April 2023, the Company presented preclinical data on IGM-8444 at the American Association for Cancer Research (AACR) Annual Meeting. The data was featured in a poster presentation titled "Characterization of the synergistic tumor cytotoxicity of agonist DR5 IgM antibody IGM-8444 with chemotherapeutic agents".

Imvotamab (CD20 x CD3)

- **Advancing into multiple autoimmune clinical trials.** The Company is planning to begin clinical testing of imvotamab in severe systemic lupus erythematosus and severe rheumatoid arthritis, subject to IND clearance.
- **Presented preclinical data.** In April 2023, the Company presented preclinical data on imvotamab at the American Association for Cancer Research (AACR) Annual Meeting. The data was featured in a poster presentation titled "Depletion of tissue-resident B cells by a CD20xCD3 IgM bispecific T cell engager in cynomolgus monkeys demonstrates effective tissue penetration and potent target cell killing".

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

- **Phase 1 trial.** The Company continues enrolling 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.

- **Presented preclinical data.** In April 2023, the Company presented preclinical data on IGM-7354 at the American Association for Cancer Research (AACR) Annual Meeting. The data was featured in a poster presentation titled "IGM-7354, an immunocytokine with IL-15 fused to an anti-PD-L1 IgM, induces NK and CD8+ T cell-mediated cytotoxicity of PD-L1-positive tumor cells".

IGM-2644 (CD38 x CD3)

- **Phase 1 trial.** The Company is initiating a 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.
- **Presented preclinical data.** In April 2023, IGM presented preclinical data evaluating IGM-2644 at the American Association for Cancer Research (AACR) Annual Meeting. The data was featured in a poster presentation titled "Novel CD38xCD3 Bispecific IgM T Cell Engager, IGM-2644, Potently Kills Multiple Myeloma Cells Though Complement and T Cell Dependent Mechanisms".

First Quarter 2023 Financial Results

- **Cash and Investments:** Cash and investments as of March 31, 2023 were $373.4 million, compared to $427.2 million as of December 31, 2022.
- **Collaboration Revenue:** For the first quarter of 2023, collaboration revenues were $0.5 million, compared to no revenue for the same period in 2022.
- **Research and Development (R&D) Expenses:** For the first quarter of 2023, R&D expenses were $50.9 million, compared to $38.9 million for the same period in 2022.
- **General and Administrative (G&A) Expenses:** For the first quarter of 2023, G&A expenses were $13.0 million, compared to $13.1 million for the same period in 2022.
- **Net Loss:** For the first quarter of 2023, net loss was $59.3 million, or a loss of $1.33 per share, compared to a net loss of $51.9 million, or a loss of $1.53 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 $45 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 more than $200 million in cash and investments, and for the balance to enable it to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2024.

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 the Company'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, the Company's technology platform and its IgM antibodies and product candidates, including IGM-8444, imvotamab, IGM-7354 and IGM-2644; the Company's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of IGM-8444, imvotamab, IGM-7354 and IGM-2644, including the timing of initiation of clinical trials, patient enrollment and release of clinical data; the Company'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 the Company'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: the Company's early stages of clinical drug development; risks related to the use of engineered IgM antibodies, which is a novel and unproven therapeutic approach; the Company's ability to demonstrate the safety and efficacy of its product candidates; the Company's ability to successfully and timely advance its product candidates through preclinical studies and clinical trials; the Company'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; the Company'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 the Company's product candidates, and the progress and success of alternative therapeutics currently available or in development; the Company'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 the Company is targeting; the Company's ability to obtain, maintain and protect its intellectual property rights; developments relating to the Company'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 the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Quarterly Report on Form 10-Q filed with the SEC on May 12, 2023 and in the Company'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 the Company specifically disclaims any obligation to update any forward-looking statement, except as required by law.

Contact:
Argot Partners
David Pitts
212-600-1902
igmbio@argotpartners.com

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

	Three Months Ended March 31,	
	2023	**2022**
Collaboration revenue	$ 522	$ —
Operating expenses:		
Research and development [1]	50,894	38,875
General and administrative [1]	13,002	13,081
Total operating expenses	63,896	51,956
Loss from operations	(63,374)	(51,956)
Other income (expense):		
Interest income	4,172	54
Other income (expense)	(20)	8
Total other income (expense)	4,152	62
Loss before income tax expense	(59,222)	(51,894)
Income tax expense	(87)	—
Net loss	$ (59,309)	$ (51,894)
Net loss per share, basic and diluted	$ (1.33)	$ (1.53)
Weighted-average common shares outstanding, basic and diluted	44,466,764	33,838,895
[1] Amounts include stock-based compensation expense as follows:		
Research and development	$ 6,439	$ 6,607
General and administrative	4,608	4,892
Total stock-based compensation expense	$ 11,047	$ 11,499

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

	March 31, 2023	**December 31, 2022**
Cash and investments	$ 373,396	$ 427,162
Total assets	462,742	513,499
Accounts payable	3,972	2,512
Accrued liabilities	29,637	33,621
Deferred revenue	148,409	148,931
Total liabilities	223,312	226,236
Accumulated deficit	(634,135)	(574,826)
Total stockholders' equity	239,430	287,263

Source: IGM Biosciences, Inc.