IGM Biosciences Announces First Quarter 2024 Financial Results and Provides Corporate Update

May 8, 2024

- Enrollment target exceeded in aplitabart randomized colorectal cancer clinical trial -

- Enrollment completed in first dose cohort in imvotamab rheumatoid arthritis clinical trial -

MOUNTAIN VIEW, Calif., May 08, 2024 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company creating and developing engineered IgM antibodies, today announced its financial results for the fiscal quarter ended March 31, 2024 and provided an update on recent developments.

"We are pleased to have exceeded our enrollment target of 110 patients in our randomized study of 3 mg/kg of aplitabart plus FOLFIRI and bevacizumab in second line colorectal cancer," said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. "While we are still scheduling first doses for a few patients, we expect that final enrollment in this clinical trial will exceed 120 patients. We are also pleased that we have completed enrollment in the first dose cohort of our clinical trial of imvotamab in severe rheumatoid arthritis."

Pipeline Updates

Aplitabart (DR5 agonist)

- **Clinical development of aplitabart advances.**
  - **Enrollment target exceeded in ongoing randomized colorectal cancer clinical trial.** The Company has exceeded its target of enrolling 110 patients in its randomized clinical trial of 3 mg/kg of aplitabart, a death receptor 5 agonist, plus FOLFIRI and bevacizumab in second-line metastatic colorectal cancer. Patients have been enrolled across multiple clinical trial sites in the United States, Asia and Europe. This randomized trial is designed to assess the benefit of 3 mg/kg of aplitabart when administered in combination with FOLFIRI and bevacizumab compared to the current standard of care treatment of FOLFIRI and bevacizumab, with a primary endpoint of progression-free survival (PFS). The release of data from this randomized clinical trial will be dependent upon the timing of PFS events in both the control and the experimental arms of this study. Based on its assumptions as to the timing of PFS events, the Company expects to be able to release top-line PFS results from this study by the end of the first quarter of 2025.
  - **Enrollment target met in 10 mg/kg dose single arm colorectal cancer clinical trial.** The Company has also met its target of enrolling 20 patients in its single arm clinical study of 10 mg/kg of aplitabart in combination with FOLFIRI and bevacizumab in the treatment of later line colorectal cancer patients.

Imvotamab (CD20 x CD3)

- **Clinical development of imvotamab in autoimmune diseases advances.**
  - **Enrollment completed in first dose cohort of imvotamab in rheumatoid arthritis.** The Company has completed enrollment in the first dose cohort of its placebo-controlled clinical study testing imvotamab in severe rheumatoid arthritis. In this first dose cohort, the Company treated six patients with imvotamab and two patients with a placebo. The Company plans to enroll two additional dose cohorts, each consisting of six patients treated with imvotamab and two patients treated with a placebo. The doses of imvotamab received in the second dose cohort are planned to be higher than those received in the first dose cohort, and the doses of imvotamab received in the third dose cohort are planned to be higher than those received in the second dose cohort. This clinical study is now being expanded to include international clinical trial sites, in addition to sites in the United States.
  - **Enrollment continues in first dose cohort of imvotamab in severe systemic lupus erythematosus.** The Company also continues to enroll patients in the first dose cohort of its single arm, open-label clinical study testing imvotamab in severe systemic lupus erythematosus (SLE). All six patients treated in the first SLE dose cohort will receive imvotamab. The Company also plans to enroll two additional dose cohorts, each consisting of six patients treated with imvotamab. The doses of imvotamab received in the second dose cohort are planned to be higher than those received in the first dose cohort, and the doses of imvotamab received in the third dose cohort are planned to be higher than those received in the second dose cohort.
  - **Enrollment to begin in myositis.** The Company is currently initiating a clinical trial of imvotamab in idiopathic inflammatory myopathies (myositis). The Company expects to begin recruiting patients for this clinical trial in the

current quarter.

IGM-2644 (CD38 x CD3)

- **Clinical development of IGM-2644 in autoimmune diseases to be initiated.** The Company continues to make plans to begin clinical development of IGM-2644, a CD38 x CD3 T cell engager antibody, in the treatment of autoimmune diseases.

First Quarter 2024 Financial Results

- **Cash and Investments:** Cash and investments as of March 31, 2024 were $293.8 million, compared to $337.7 million as of December 31, 2023.
- **Collaboration Revenue:** For the first quarter of 2024 and 2023, collaboration revenues were $0.5 million in each quarter.
- **Research and Development (R&D) Expenses:** For the first quarter of 2024, R&D expenses were $43.8 million, compared to $50.9 million for the first quarter of 2023.
- **General and Administrative (G&A) Expenses:** For the first quarter of 2024, G&A expenses were $10.5 million, compared to $13.0 million for the first quarter of 2023.
- **Net Loss:** For the first quarter of 2024, net loss was $49.8 million, or a loss of $0.83 per share, compared to a net loss of $59.3 million, or a loss of $1.33 per share, for the first quarter of 2023.

2024 Financial Guidance

The Company expects full year 2024 GAAP operating expenses of $210 million to $220 million including estimated non-cash stock-based compensation expense of approximately $40 million. As a result of the refocusing of the Sanofi collaboration announced in April 2024, the Company expects to recognize full year collaboration revenue of approximately $63 million, of which $62 million is expected to be recognized in the second quarter of 2024. This collaboration revenue relates to accounting recognition of the upfront $150 million payment received from Sanofi in 2022 and will not impact the Company's cash balance or runway. The Company expects to end 2024 with a balance of approximately $180 million in cash and investments and for the balance to enable it to fund its operating expenses and capital expenditure requirements into the second quarter of 2026.

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 and autoimmune and inflammatory 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 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, and IGM-2644; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of aplitabart, imvotamab, and IGM-2644, including the timing of clinical trial initiation, expected patient enrollment, expected dosing, expected expansion to international clinical trial sites, and the timing of the release of data; IGM's expectations regarding its financial position and projected cash runway; expected impact of the refocusing of the Sanofi collaboration on the Company's recognition of revenue; 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; uncertainties related to IGM's ability to realize the contemplated benefits of its pipeline prioritization efforts and related reduction in force; 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 May 8, 2024 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 March 31,	
	2024	**2023**
Collaboration revenue	$ 497	$ 522
Operating expenses:		
Research and development[(1)]	43,815	50,894
General and administrative[(1)]	10,538	13,002
Total operating expenses	54,353	63,896
Loss from operations	(53,856)	(63,374)
Other income (expense):		
Interest income	4,040	4,172
Other expense	—	(20)
Total other income (expense)	4,040	4,152
Loss before income tax expense	(49,816)	(59,222)
Income tax expense	—	(87)
Net loss	$ (49,816)	$ (59,309)
Net loss per share, basic and diluted	$ (0.83)	$ (1.33)
Weighted-average common shares outstanding, basic and diluted	60,114,409	44,466,764
[(1)]Amounts include stock-based compensation expense as follows:		
Research and development	$ 4,362	$ 6,439
General and administrative	3,560	4,608
Total stock-based compensation expense	$ 7,922	$ 11,047

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

	March 31, 2024	**December 31, 2023**
Cash and investments	$ 293,768	$ 337,677
Total assets	376,132	423,411
Accounts payable	3,995	1,326
Accrued liabilities	23,652	31,544
Deferred revenue	146,304	146,801
Total liabilities	214,879	220,177
Accumulated deficit	(871,058)	(821,242)
Total stockholders' equity	161,253	203,234

Source: IGM Biosciences, Inc.