IGM Biosciences Announces Strategic Pipeline Prioritization and Cash Runway Extension

December 5, 2023

– Priorities: clinical development of DR5 agonist in colorectal cancer and T cell engagers in autoimmune disease –

– Plans to file IND for IGM-2644 (CD38 x CD3) to treat autoimmune disease –

– All clinical development in hematologic oncology indications halted –

– Cash runway expected to extend into second quarter 2026 –

– Reduction in workforce of approximately 22 percent –

MOUNTAIN VIEW, Calif., Dec. 05, 2023 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company creating and developing engineered IgM antibodies, today announced that it will focus its resources in two strategic areas: (i) treating colorectal cancer using IgM death receptor 5 (DR5) agonist antibodies, and (ii) treating autoimmune diseases using IgM T cell engager antibodies. As an expansion of its autoimmune efforts, the Company also announced today that it plans to file an Investigational New Drug (IND) application to begin the clinical development of IGM-2644, its CD38 x CD3 T cell engager antibody, for the treatment of autoimmune diseases. As part of its strategic refocus, the Company is halting all hematologic oncology clinical development as well as the clinical development of its targeted cytokine product candidate. The Company will continue to focus on the development of oncology and immunology and inflammation product candidates under its collaboration with Sanofi. In conjunction with this strategic refocusing, the Company will be reducing its workforce by approximately 22 percent. As a result of these actions, IGM expects to extend its cash runway into the second quarter of 2026.

“IGM continues to have a tremendous opportunity to transform a variety of disease areas using an entirely new class of antibody medicines,” said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. “Although we are very encouraged by the clinical and preclinical data that we have generated for the programs we are halting, given the difficult conditions in the capital markets for our industry, we have decided to focus our capital resources on those opportunities that we believe have the most potential to produce significant near-term value. We are very sorry that some of our dedicated and talented employees will be leaving IGM as part of this strategic refocusing, and we wish to extend our sincere thanks and assistance to them in this difficult transition.”

Pipeline Update:

Aplitabart (DR5 agonist)

- **Clinical development of aplitabart in colorectal cancer prioritized.**
  - **Enrollment continues in 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 trial sites in the United States, this trial includes multiple clinical trial sites in Asia and Europe.
  - **Treatment at 10 mg/kg ongoing in the single arm colorectal cancer clinical trial continues.** The Company also 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.

Imvotamab (CD20 x CD3)

- **Clinical development of imvotamab in autoimmune diseases prioritized.** The Company is prioritizing the clinical development of imvotamab, an IgM-based CD20 x CD3 bispecific T cell engaging antibody in autoimmune diseases. The Company currently has two Phase 1b clinical trials underway, one in severe systemic lupus erythematosus (SLE) and one in severe rheumatoid arthritis (RA). These clinical trials are being expanded to include multiple U.S. and international clinical trial sites. The Company also recently received clearance from the FDA of its IND application for the use of imvotamab in treating idiopathic inflammatory myopathies (myositis), and preparations are underway to move this clinical trial forward.

IGM-2644 (CD38 x CD3)

- **Clinical development of IGM-2644 in autoimmune diseases prioritized.** The Company is prioritizing the clinical development of IGM-2644, a CD38 x CD3 T cell engager antibody, in the treatment of autoimmune diseases, and it plans

to file an IND for these purposes in 2024.

As a part of this strategic refocusing, the Company will halt the following clinical development activities:

- Aplitabart in acute myeloid leukemia and in combination with birinapant
- IGM-2644 (CD38 x CD3) in multiple myeloma
- IGM-2537 (CD123 x CD3)
- IGM-7354 (IL-15 x PD-L1)

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 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, 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, patient enrollment and IND submissions; IGM's expectations regarding its financial position 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; 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 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.

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

Source: IGM Biosciences, Inc.