IGM Biosciences Announces Update on IGM-8444 Phase 1 Trial and Future Clinical Development

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– Initial Data from Phase 1 combination with FOLFIRI shows promising activity in heavily pretreated metastatic colorectal cancer patients –

– Encouraging safety profile in combination with FOLFIRI chemotherapy –

– Randomized combination trial in second-line colorectal cancer patients to initiate in Q1 2023 –

MOUNTAIN VIEW, Calif., Jan. 09, 2023 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing IgM antibodies, today announced an update on its clinical development program for IGM-8444, a novel multivalent DR5 agonist, and announced plans for a new randomized combination trial in patients with metastatic colorectal cancer.

Initial Phase 1 data reported from a cohort of patients with combination treatment of IGM-8444 and FOLFIRI showed an encouraging safety profile which was broadly comparable to that expected from chemotherapy alone in this setting. Specifically, there was no drug related clinically significant hepatotoxicity, with only grade 1 and grade 2 transient liver enzyme elevations observed.

In patients with metastatic colorectal cancer, the combination of IGM-8444 and FOLFIRI showed promising activity, with multiple confirmed responses observed even in patients who had previously progressed on FOLFIRI. In 13 metastatic patients treated with doses of IGM-8444 from 1 to 10 mg/kg plus standard doses of FOLFIRI chemotherapy, there were four responses observed (three confirmed at 3mg/kg), and one additional patient had substantial tumor shrinkage allowing for subsequent complete surgical resection. Responses occurred in patients with KRAS wild type and mutated tumors and in patients with or without liver metastases. The majority of patients were on their third line of treatment or beyond and 10 of the 13 patients had previously been treated with FOLFIRI chemotherapy. Median progression free survival (PFS) among nine 3L+ patients was 5.5 months, with the longest observed PFS extending beyond 12 months. A more detailed presentation of the results is available on the Company's website at www.igmbio.com.

Based on these results, the Company is initiating a randomized trial in second line patients with metastatic colorectal cancer to assess the additional benefit of IGM-8444 combined with the current standard of care regimen of FOLFIRI and bevacizumab. This open label trial is planned to begin in Q1 2023.

"We are very pleased with the initial results observed with IGM-8444," said Chris Takimoto, M.D., Ph.D., F.A.C.P., Chief Medical Officer of IGM Biosciences. "We are also quite pleased with the excellent safety profile seen in these patients. The absence of clinically significant hepatotoxicity, which has been challenging for DR5 agonists in the past, is particularly important. These responses, especially in patients who have previously failed chemotherapy, are very encouraging and give us confidence in proceeding to further clinical development with FOLFIRI and other combination agents. The planned randomized trial with FOLFIRI will expand our understanding of this activity and enable better understanding of the potential for IGM-8444 in patients with colorectal cancer."

"These initial IGM-8444 clinical results represent an important step in demonstrating the potential of our IgM antibody platform to overcome the long history of failure with conventional IgG antibodies targeting DR5," said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. "We believe these results also help support the potential for IgM antibodies as agonists against the broader TNF receptor super family, and we look forward to accelerating our company-wide efforts to develop a new class of agonist antibody medicines, including through our collaboration with Sanofi."

About IGM-8444
IGM-8444 is an IgM antibody targeting Death Receptor 5 (DR5) that is being developed for the treatment of patients with solid and hematologic malignancies. DR5 is a member of the tumor necrosis factor receptor superfamily (TNFrSF) and is often expressed on the surface of cancer cells. Strong activation of the DR5 pathway requires multiple receptors to be cross-linked simultaneously by an antibody or other binding agent to create an apoptotic death signal to the cell. Unlike traditional IgG antibodies, IGM-8444 has 10 binding units, enabling it to cross-link multiple DR5 receptors at the same time, sending a stronger signal to cause cancer cell death.

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, infectious diseases and autoimmune and inflammatory 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 IGM-8444; IGM's plans and expectations regarding the clinical development of IGM-8444, including the timing of initiation of a randomized clinical trial of IGM-8444; and statements by IGM's Chief Executive Officer and Chief Medical 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: potential delays and disruption resulting from the COVID-19 pandemic and governmental responses to the pandemic, including any

future impacts to IGM's operations, the manufacture of its product candidates, the progression of its clinical trials, and enrollment in its current and future clinical trials; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of collaborations with third parties; 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; 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; general economic and market conditions; 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 3, 2022 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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