IGM Biosciences Announces FDA Clearance to Begin Clinical Studies of Imvotamab in Lupus and Rheumatoid Arthritis

May 31, 2023

Imvotamab, a CD20 x CD3 bispecific monoclonal antibody, offers potential for deeper B cell depletion than currently approved therapies

MOUNTAIN VIEW, Calif., May 31, 2023 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing IgM antibodies, today announced that the U.S. Food and Drug Administration (FDA) has cleared two Investigational New Drug (IND) applications for imvotamab, an IgM-based CD20 X CD3 bispecific antibody T cell engager, enabling the initiation of Phase 1b studies in both severe systemic lupus erythematosus (SLE) and severe rheumatoid arthritis (RA). The Company plans to begin patient enrollment in both multicenter clinical studies in the third quarter of 2023.

"Treating autoimmune disease with T cell engagers is an exciting new field of therapeutic research, and we believe imvotamab, with its potential for deep B cell depletion, offers the opportunity to lead and transform treatment in this area," said Mary Beth Harler, M.D., President, IGM Autoimmunity and Inflammation. "Over the last two decades, CD20 has become well-established as a therapeutic target in multiple autoimmune diseases. The data from our non-Hodgkin's lymphoma clinical studies indicate that imvotamab can deplete CD20 expressing B cells, even rapidly growing lymphoma cells, with a favorable safety profile as compared with other T cell engaging CD20 x CD3 antibodies. Emerging data with cell-based therapies suggest that deep B cell depletion may have the potential to reset the immune system in patients with certain autoimmune diseases. We look forward to initiating these Phase 1b clinical trials for patients with SLE and RA in the third quarter of 2023 and fully developing the potential of imvotamab and other IgM based T cell engagers in autoimmune diseases."

The primary outcome measure of the Phase 1b SLE and RA clinical trials will be the safety, tolerability, pharmacokinetics, pharmacodynamics and biologic activity of imvotamab in patients with severe SLE and severe RA who have failed multiple prior therapies. In preclinical *in vivo* studies, imvotamab has demonstrated deep B cell depletion within tissues, where depletion of pathogenic immune cells may be critical to long-term clinical benefit in autoimmune diseases. Imvotamab has also demonstrated in preclinical *in vitro* studies that it can be more effective in depleting B cells with low levels of CD20 expression as compared to rituximab. Further, recently reported results from the Company's Phase 1 and Phase 2 non-Hodgkin's lymphoma (NHL) studies demonstrated an incidence of cytokine release syndrome (CRS) that was lower than the rates of CRS reported for other T cell engaging bispecific CD20 x CD3 antibodies in comparable NHL clinical studies.

About Imvotamab (IGM-2323)
Imvotamab is a novel IgM-based CD20 x CD3 bispecific antibody T cell engager (TCE). Preclinical research demonstrates that imvotamab may have advantages over IgG bispecific antibodies including greater binding power to CD20 expressing cells especially when CD20 expression levels are low.

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's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of imvotamab, including the initiation of clinical trials and patient enrollment; and statements by IGM's President, IGM Autoimmunity and Inflammation. 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 initiate and 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; 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 Quarterly Report on Form 10-Q filed with the SEC on May 12, 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.