

IGM Biosciences to Present First Clinical Data from IGM-2323 in Non-Hodgkin's Lymphoma at 2020 ASH Annual Meeting

November 4, 2020

- Abstract Shows Encouraging Safety and Cytokine Release Data, Preservation of T cell Function and Repeatable T cell

Activation -

MOUNTAIN VIEW, Calif., Nov. 04, 2020 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies, today announced that it expects the first clinical data from its Phase 1 trial evaluating IGM-2323 will be presented at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition, which will be held virtually. IGM-2323 is a bispecific IgM antibody targeting the CD20 protein on the surface of lymphoma cells and the CD3 protein on the surface of T cells in order to kill lymphoma cells in patients with non-Hodgkin's lymphoma (NHL). The Company's multicenter, open-label Phase 1 clinical trial is intended to assess the safety, pharmacokinetics and preliminary efficacy of intravenous IGM-2323 in patients with relapsed/refractory B cell NHL.

The preliminary results are expected to be presented on Saturday, December 5, 2020, at 7:00 a.m. PT, in an oral poster presentation titled "Preliminary Results of a Phase 1 Dose Escalation Study of the First-in-Class IgM Based Bispecific Antibody IGM-2323 (anti-CD20 x anti-CD3) in Patients with Advanced B-Cell Malignancies." At the time of the ASH Annual Meeting, IGM plans to present additional safety, pharmacokinetic, biomarker and efficacy data from the eight patients described in the abstract released today (Budde et. al., abstract #134983) and from additional patients treated subsequent to the data cut-off for the abstract. IGM is currently enrolling patients for treatment with 300 mg, but data from this dose cohort will not be available by the time of the ASH Annual Meeting.

As described in the abstract, as of June 12, 2020, eight patients had been treated at 4 dose levels (0.5, 2.5, 10, and 30 mg). The eight patients had received an average of four prior therapies before treatment with IGM-2323. Six of the eight patients remained on active treatment as of the data cut-off for the abstract. No dose limiting toxicities (DLTs) or drug related serious adverse events (SAEs) had been observed among the eight patients. Two patients had experienced low-grade transient fevers, but no grade 2 or higher cytokine release syndrome had been observed among the eight patients. When cytokines were detectable following dosing, they were transient and had returned to baseline at less than 6-12 hours. Interferon-gamma (IFNg) was the primary cytokine observed, with significant levels of IL-6 detected in only one patient. Preliminary results from this first-in-human T cell engaging antibody study show an improved safety and tolerability profile. There is also evidence of a novel mechanism of action based on repeatable T cell activation and preservation of T cell function compared with other T cell engaging antibodies.

"We are very pleased with the clinical data described in the abstract from the first-in-human clinical testing of an engineered IgM antibody," said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. "We believe that these data provide an important initial validation of the IGM T cell engaging bispecific technology and the broader IGM antibody technology platform. We look forward to the continued development of IGM-2323, IGM-8444 and our extensive pipeline of IgM antibodies."

"It is very encouraging to see evidence of a repeatable immune activation of T cells," said Daniel Chen M.D., Ph.D., Chief Medical Officer of IGM Biosciences. "This is in contrast to the T cell activation profile of other T cell engagers and CAR-T cells and suggests that IGM-2323 is activating T cells in a manner which is different from IgG and fragment-based T cell engagers and which preserves T cell function and repeatable T cell activation. We look forward to presenting our initial clinical results at ASH, continuing the development of IGM-2323 and applying this novel T cell engager technology to additional hematologic and solid tumor targets and indications."

About IGM Biosciences, Inc.

Headquartered in Mountain View, California, IGM Biosciences is a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies. Since 2010, IGM Biosciences has worked to overcome the manufacturing and protein engineering hurdles that have limited the therapeutic use of IgM antibodies. Through its efforts, IGM Biosciences has created a proprietary IgM technology platform for the development of IgM antibodies for those clinical indications where their inherent properties may provide advantages as compared to IgG antibodies.

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, the Company's IgM technology platform, IGM-2323 and its other IgM antibodies, statements regarding the Company's Phase 1 clinical trial of IGM-2323, the timing of reporting initial clinical data from the Phase 1 trial of IGM-2323, the presentation of initial clinical data from the Phase 1 trial of IGM-2323 at the ASH Annual Meeting in December, the Company's development strategy for IGM-2323, 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; 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; the risk that IGM-2323 or IGM's other product candidates may cause significant adverse events, toxicities or other undesirable side effects; the potential for clinical trials of IGM-2323 or IGM-8444, or any future clinical trials of other product candidates, to differ from preclinical, preliminary or expected results: the risk that initial, interim, topline or preliminary data from IGM's clinical trials may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the later or final data; IGM's ability to adequately demonstrate sufficient safety and efficacy of IGM-2323 and its other product candidates; IGM's ability to advance product candidates into, and successfully complete, clinical trials on the timelines it projects; the risk that all necessary regulatory approvals cannot be obtained; IGM's ability to enroll patients in its ongoing and future clinical trials; IGM's ability to successfully manufacture and supply its product candidates for clinical trials; 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 Annual Report on Form

10-K filed with the SEC on March 26, 2020, IGM's Quarterly Report on Form 10-Q filed with the SEC on August 6, 2020 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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Source: IGM Biosciences