IGM Biosciences Presents Clinical Data from IGM-2323 in Patients with Advanced B Cell Malignancies at 2021 American Society of Hematology Annual Meeting

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- Data Presented Shows Novel Bispecific IgM Antibody is Active in Heavily Pre-treated Patients with Relapsed/Refractory NHL, including DLBCL and FL, and has a Favorable Safety Profile -

- Phase 2 Clinical Trials in DLBCL and FL and Combination Clinical Trials to be Initiated -

- Company to Host Conference Call and Webcast Today at 7:30 p.m. EST -

MOUNTAIN VIEW, Calif., Dec. 11, 2021 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies, today announced the presentation of clinical results from the Company's Phase 1 trial evaluating IGM-2323, a novel bispecific IgM antibody targeting CD20 x CD3, at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition. The data was featured today in an oral presentation titled "A Phase 1 Dose Escalation Study of IGM-2323, a Novel Anti-CD20 x Anti-CD3 IgM T Cell Engager (TCE) in Patients with Advanced B-Cell Malignancies".

The multicenter, open-label Phase 1 dose escalation trial was intended to assess the safety, pharmacokinetics and preliminary efficacy of intravenous IGM-2323 in patients with advanced B cell malignancies. As of September 10, 2021, the data cutoff date for the presentation, 40 patients were enrolled and treated at escalating dose levels of IGM-2323.

All 40 patients received at least one dose and were evaluable for safety. There were no dose limiting toxicities (DLTs), no neurotoxicity adverse events (AEs), a relatively low rate of cytokine release syndrome (CRS) and no patients discontinued due to an AE.

Of the 10 patients treated in the 100 mg cohort, 3 of 6 diffuse large B cell lymphoma (DLBCL) patients had a complete response and 2 of 3 follicular lymphoma (FL) patients had a complete response. Additionally, the one mantle cell patient treated in the 100 mg dose cohort had a partial response. Overall, of the 38 patients evaluable for efficacy, 11 patients showed a response, 8 of which were complete responses.

Based on these promising results, two Phase 2 studies are being initiated to assess the safety and efficacy of two doses of IGM-2323, 100 mg and 300 mg, in patients with DLBCL and FL. If supportive, the data from this Phase 2 multicenter, open-label study could potentially be used as the basis for accelerated review and approval of IGM-2323.

"Data presented today demonstrate that IGM-2323 is highly active against multiple subtypes of relapsed/ refractory non-Hodgkin's lymphoma and shows an excellent safety profile with low rates of CRS, no CRS-associated neurotoxicity and minimal neutropenia," said Dr. Elizabeth Budde, M.D., Ph.D., Assistant Professor, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope National Medical Center. "Results to date from this Phase 1 study are encouraging, and I look forward to continuing to investigate this important novel therapy's potential in these difficult-to-treat disease areas. Patients with non-Hodgkin's lymphoma need efficacious and well-tolerated treatments, and IGM-2323 is potentially well-suited to help with this unmet need."

"We are pleased to show multiple complete responses in patients with diffuse large B cell lymphoma and follicular lymphoma at the 100 mg dose level and encouraging, consistent safety data," said Chris Takimoto, M.D., Ph.D., F.A.C.P., Chief Medical Officer of IGM Biosciences. "We are excited to continue the development of IGM-2323 by moving forward with our Phase 2 expansion studies and by initiating combination studies in earlier lines of treatment. We believe these clinical results are also encouraging for the development of the IgM T cell engagers targeting CD38 and CD123 in our hematologic pipeline."

Conference Call and Webcast
The conference call may be accessed by dialing (866) 649-1996 (domestic) or (409) 217-8769 (international) and referring to conference ID 9695193. A live webcast of the presentation will be available on the "Events and Presentations" page in the "Investors" section of the Company's website at https://investor.igmbio.com/news-and-events/events-and-presentations. A replay of the webcast will be archived on the Company's website for 90 days following the presentation.

About IGM-2323
IGM-2323 is a CD20 x CD3 bispecific IgM antibody designed to treat patients with B cell non-Hodgkin's lymphoma (NHL) and other B cell malignancies. CD20 is a protein that is frequently expressed on the surface of malignant B cells, while CD3 is a protein that is expressed on the surface of T cells and is an essential activating molecule of the T cell. IGM-2323 has 10 binding domains to CD20 and a single binding domain to CD3 (specifically CD3ε).

IGM-2323 is designed to simultaneously and stably bind a CD20 expressing cancer cell as well as CD3 on a cytotoxic T cell, bringing both cells into close proximity. This interaction mimics the normal T cell activation pathway leading the T cell to recognize and kill the cancer cell by releasing cytotoxic biochemicals (perforins and granzymes) that penetrate and perforate the cancer cell. In contrast to other bispecific antibody formats that bind to one or two CD20 molecules on the surface of the cancer cell and to one CD3 molecule on the surface of the T cell, IGM-2323 has 10 binding units to CD20 and one binding unit to CD3. The Company believes that IGM-2323 with its 10 binding units for CD20 may successfully bind to CD20 expressing cancer cells with more avidity compared to an IgG bispecific antibody with only one binding unit for CD20.

IGM-2323 also employs an additional mechanism to kill CD20 expressing cancer cells, known as complement dependent cytotoxicity (CDC). CDC is a mechanism by which antibodies can mediate specific targeted cell killing by activating the complement system. Components of the complement system are naturally present in humans, and IgM antibodies are the most efficient antibodies at engaging the complement system for CDC, with an approximately 100-fold increase in CDC relative to comparable IgG CD20 antibodies.

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, IGM's technology platform and its IgM antibodies and product candidates, including IGM-2323; IGM's plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of IGM-2323, including IGM's plans to initiate two Phase 2 studies of IGM-2323, the design of such studies, expectations regarding dosing and the potential for accelerated approvals and such Phase 2 studies serving as potentially registrational studies; and statements by IGM's 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 manufacturing of its product candidates, the progression of its clinical trials, enrollment in its current and future clinical trials and progression of its collaborations and related efforts; 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, the potential diminishing need for therapeutics to address COVID-19, particularly in the United States and other major markets, 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; risks related to collaborations with third parties, including the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of any such collaboration; 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 30, 2021, IGM's Quarterly Report on Form 10-Q filed with the SEC on November 4, 2021 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.