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

December 5, 2020

- 9 of 14 Patients Showed Reduction in Tumor Size, Including Two Recently Reported Complete Responses -

- Company to Host Conference Call and Webcast Today at 2:00 p.m. ET -

MOUNTAIN VIEW, Calif., Dec. 05, 2020 (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 preliminary clinical results from the Company's Phase 1 trial evaluating IGM-2323, a bispecific IgM antibody targeting CD20 x CD3, at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition. The data was featured today in a 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" (Abstract number 1142).

The multicenter, open-label Phase 1 dose escalation trial is intended to assess the safety, pharmacokinetics and preliminary efficacy of intravenous IGM-2323 in patients with relapsed/refractory B cell non-Hodgkin's lymphoma (NHL). As of October 30, 2020, the data cutoff date for the presentation, 16 patients were enrolled and treated at escalating dose levels of IGM-2323. Dose escalation continues in the study toward the anticipated recommended Phase 2 dose (RP2D) range of between 100 and 1000 mg.

Of the 14 patients treated in the 0.5, 2.5, 10, 30 and 50/100 mg dose cohorts, nine showed evidence of tumor size reduction and two patients showed partial responses (PRs), including a patient with follicular lymphoma (50/100 mg dose level) and a patient with diffuse large B cell lymphoma (DLBCL) who had failed CAR-T therapy (30 mg dose level). Subsequent to the data cutoff, the two patients with follicular lymphoma treated at the 50/100 mg titration dose converted to complete responses (CRs).

Dose titration has been introduced at the higher dose levels to provide NHL patients with optimal and repeatable immune activity. The study is currently enrolling for the 50/300 mg titration dose cohort. Of the three patients at the 50/100 mg titration dose and one patient at the 50/300 mg titration dose, none have exhibited fever, chills, cytokine release syndrome (CRS) or neurotoxicity to date. Among all patients, IGM-2323 was found to be generally well tolerated, with no dose limiting toxicities, no Grade 3 or higher CRS and no evidence of neurotoxicity observed, despite less steroid pretreatment than used in studies of most other T cell engagers. Three Grade 1 CRS events (low-grade fever/chills) were reported in the lower dose groups, and one Grade 2 CRS event was observed at the first infusion in the non-titrated 100 mg dose level in a patient with pre-existing severe hypertension who was receiving four anti-hypertensive medications.

IFN-dominant cytokine secretion with little to no measurable circulating IL-6 or TNFα was observed in most patients treated at ≥ 10 mg of IGM-2323, an observation that contrasts with studies of most other T cell engagers. No drug-induced anti-drug antibodies were observed, and preliminary PK results were consistent with preclinical data.

"Bispecific antibodies that bridge lymphoma cells to T cells have shown promise in treating B cell malignancies, but existing T cell engaging antibodies are often associated with toxicity, especially CRS, and have a limited therapeutic window potentially related to downregulation of T cell function," said Elizabeth Budde, M.D., Ph.D., Assistant Professor, Department of Hematology and Hematopoietic Cell Transplantation, City of Hope National Medical Center. "IGM-2323 may provide more physiologic T cell activation, with evidence for preservation of T cell activation in the majority of patients in this study, as compared with the global reduction in T cell function associated with existing bispecific T cell engaging antibodies. Initial results from this Phase 1 study are particularly encouraging, and I look forward to determining the recommended Phase 2 dose and more fully elucidating the activity and safety of IGM-2323 in larger outcome studies."

"IGM-2323 may uniquely limit supraphysiologic stimulation of T cells, potentially leading not just to improved safety and tolerability, but also to more physiologic levels of T cell stimulation, which in turn may preserve or strengthen T cell responsiveness and further enhance anti-cancer activity over time," said Daniel Chen M.D., Ph.D., Chief Medical Officer of IGM Biosciences. "It is very encouraging to see evidence of this repeatable immune activation of T cells this early in our Phase 1 study. We look forward to the continued development of IGM-2323 and to applying this novel T cell engager technology to additional hematologic and solid tumor targets and indications."

"These are the first-in-human clinical results of an engineered IgM antibody, and we are very pleased with both the tolerability and initial activity observed to date, both of which are consistent with our expectations for this novel technology," said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. "These data provide an important initial validation of the IGM T cell engaging bispecific technology and the broader IGM antibody technology platform, from which we expect to see a growing body of clinical data. We look forward to the continued development of IGM-2323, IGM-8444 and our extensive pipeline of IgM antibodies."

In addition to the IGM-2323 presentation, IGM will also present preclinical findings from IGM-8444, the Company's agonistic death receptor 5 (DR5) IgM antibody, in a poster presentation titled "The Anti-Tumor Activity of Igm-8444, an Agonistic Death Receptor 5 (DR5) IgM Antibody, Is Sensitized in Combination with Chemotherapy and Bcl-2 Inhibitors in NHL and AML" (Abstract number 2093) at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition. The poster presentation will be available at the 2020 ASH Annual Meeting and Exposition tomorrow, December 6, 2020, at 7:00 a.m. PT (or 10:00 a.m. ET), as part of the session titled "Lymphoma: Pre-Clinical—Chemotherapy and Biologic Agents: Poster II." IGM is currently enrolling patients in a Phase 1 study of IGM-8444 as a single agent and in combination with chemotherapy-based regimens in subjects with solid tumors. The first dose cohort of the single-agent portion of this study is now complete, and the second dose cohort is currently enrolling.

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 1141638.

A live webcast of the presentation will be available on the “Events and Presentations” page on 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 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, bispecific antibodies, the Company’s IgM technology platform, its IgM antibodies and IGM-2323 and IGM-8444, statements regarding the Company’s Phase 1 clinical trials of IGM-2323 and IGM-8444, the Company’s development strategy for IGM-2323 and IGM-8444, and statements by Dr. Budde, Mr. Schwarzer and Dr. Chen. 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 on 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 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 adequately demonstrate sufficient safety and efficacy of its product candidates; IGM’s ability to enroll patients in its ongoing and future clinical trials; the potential for the results of clinical trials of IGM-2323, IGM-8444 or any future clinical trials of other product candidates to differ from preclinical, preliminary or expected results; the risk that IGM-2323 or IGM-8444 may cause significant adverse events, toxicities or other undesirable side effects; 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 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; 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 26, 2020, IGM’s Quarterly Report on Form 10-Q filed with the SEC on November 5, 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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