IGM Biosciences and ADC Therapeutics Announce Clinical Collaboration Agreement to Evaluate Imvotamab (IGM-2323) in Combination with ZYNLONTA® in Patients with Relapsed or Refractory B Cell Non-Hodgkin’s Lymphoma

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– Companies to Leverage Lead Product Candidate from IGM’s Proprietary IgM Antibody Platform with ZYNLONTA® for Novel Combination Therapy in Relapsed/Refractory B Cell NHL –

– Phase 1 Trial Expected to be Initiated in 1Q23 –

MOUNTAIN VIEW, Calif. and LAUSANNE, Switzerland, Nov. 02, 2022 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing IgM antibodies, and ADC Therapeutics SA (NYSE: ADCT) today announced that they have entered into a clinical trial collaboration and supply agreement to evaluate the combination of imvotamab, IGM’s novel IgM CD20 x CD3 T cell engaging bispecific antibody, and ZYNLONTA® (loncastuximab tesirine-lpyl), ADC Therapeutics’ CD19-directed antibody drug conjugate (ADC), for the treatment of patients with relapsed/refractory (R/R) B cell non-Hodgkin’s lymphoma (NHL).

“Patients with B cell non-Hodgkin’s lymphoma are in need of efficacious and well-tolerated treatments,” said Chris Takimoto, M.D., Ph.D., F.A.C.P., Chief Medical Officer of IGM Biosciences. “We are excited to enter this collaboration with ADC Therapeutics that aims to provide a novel combination regimen targeting both CD19- and CD20-expressing cells for patients with relapsed/refractory B cell non-Hodgkin’s lymphoma. We look forward to working with the team at ADC Therapeutics and initiating clinical testing in the first quarter of 2023.”

In data previously reported at the 2021 American Society of Hematology (ASH) Annual Meeting, imvotamab showed a 50% complete response (CR) rate at the likely optimal 100 mg dose (n=10). Of the 28 patients treated in the titration dosing cohorts at that time, cytokine release syndrome was seen in less than 20% of patients.

“We are pleased to collaborate with IGM Biosciences to explore ZYNLONTA in combination with imvotamab,” said Joseph Camardo, M.D., Chief Medical Officer of ADC Therapeutics. “This collaboration extends ADC Therapeutics’ commitment to maximizing the potential of our CD19-directed ADC for patients with significant unmet medical needs, both as a single agent and in novel combinations with other anti-cancer agents. The safety profile of imvotamab and the activity observed so far in Phase 1 are highly promising for future development.”

Under the terms of the agreement, IGM will be responsible for conducting clinical testing to evaluate the safety and efficacy of imvotamab in combination with ZYNLONTA® for the treatment of patients with R/R NHL. ADC Therapeutics will provide clinical expertise on ZYNLONTA® as well as drug supply to support the trial. IGM expects to initiate the trial in the first quarter of 2023. The clinical collaboration is based on compelling mechanistic rationale and preclinical data showing strong activity of this approach.

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.

About Imvotamab (IGM-2323)
Imvotamab is a novel IgM-based CD20 x CD3 bispecific antibody T cell engager (TCE) with the therapeutic potential to be a backbone treatment in hematologic. Preclinical research demonstrates that imvotamab may have advantages over IgG bispecific antibodies including greater binding power to CD20 expressing cancer cells especially when CD20 expression has been reduced due to prior treatment with anti-CD20 antibodies. It has also been shown to have good target cell killing efficacy combined with a lower cytokine release profile associated with the T cell directed cellular cytotoxicity (TDCC) mechanism. Data generated from Phase 1 clinical trials provide evidence that imvotamab exhibits a favorable safety and tolerability profile with promising activity in refractory or relapsed NHL patients. Imvotamab is currently being studied in two Phase 2 trials to assess the safety and efficacy of two doses 100 mg and 300 mg, in patients with diffuse large B cell lymphoma (DLBCL) and follicular lymphoma (FL).

About ZYNLONTA® (loncastuximab tesirine-lpyl)
ZYNLONTA® is a CD19-directed antibody drug conjugate (ADC). Once bound to a CD19-expressing cell, ZYNLONTA is internalized by the cell, where enzymes release a pyrolobenozidinepine (PBD) payload. The potent payload binds to DNA minor groove with little distortion, remaining less visible to DNA repair mechanisms. This ultimately results in cell cycle arrest and tumor cell death.

The U.S. Food and Drug Administration (FDA) has approved ZYNLONTA (loncastuximab tesirine-lpyl) for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphomas after two or more lines of systemic therapy, including DLBCL not otherwise specified, DLBCL arising from low-grade lymphomas and also high-grade B-cell lymphomas. The trial included a broad spectrum of heavily pre-treated patients (median three prior lines of therapy) with difficult-to-treat disease, including patients who did not respond to first-line therapy, patients refractory to all prior lines of therapy, patients with double/triple hit genetics and patients who had stem cell transplant and CAR-T therapy prior to their treatment with ZYNLONTA. This...
ZYNLONTA is also being evaluated as a therapeutic option in combination studies in other B-cell malignancies and earlier lines of therapy.

About ADC Therapeutics
ADC Therapeutics (NYSE: ADCT) is a commercial-stage biotechnology company improving the lives of those affected by cancer with its next-generation, targeted antibody drug conjugates (ADCs). The Company is advancing its proprietary PBD-based ADC technology to transform the treatment paradigm for patients with hematologic malignancies and solid tumors.

ADC Therapeutics’ CD19-directed ADC ZYNLONTA (loncastuximab tesirine-lpyl) is approved by the FDA for the treatment of relapsed or refractory diffuse large b-cell lymphoma after two or more lines of systemic therapy. ZYNLONTA is also in development in combination with other agents. Cami (camidanlumab tesirine) is being evaluated in a pivotal Phase 2 trial for relapsed or refractory Hodgkin lymphoma and in a Phase 1b clinical trial for various advanced solid tumors. In addition to ZYNLONTA and Cami, ADC Therapeutics has multiple ADCs in ongoing clinical and preclinical development.

ADC Therapeutics is based in Lausanne (Biopôle), Switzerland and has operations in London, the San Francisco Bay Area and New Jersey. For more information, please visit https://adctherapeutics.com/ and follow the Company on Twitter and LinkedIn.

ZYNLONTA® is a registered trademark of ADC Therapeutics SA.

IGM Biosciences 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; expectations regarding the agreement with ADC Therapeutics; IGM’s plans and expectations regarding its clinical development efforts and activities; statements regarding the clinical development of IGM-2323, including the timing of initiation of a Phase 1 trial in combination with Zynlonta; 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 manufacture 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; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of collaborations with third parties, including the agreement with Sanofi; 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 most recent Quarterly Report on Form 10-Q filed with the SEC on August 8, 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.

ADC Therapeutics Forward-Looking Statements
This press release contains statements that constitute forward-looking statements. All statements other than statements of historical facts contained in this press release, including statements regarding our future results of operations and financial position, cash runway, business and commercial strategy, market opportunities, products and product candidates, research pipeline, ongoing and planned preclinical studies and clinical trials, regulatory submissions and approvals, projected revenues and expenses and the timing of revenues and expenses, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including those described in our filings with the U.S. Securities and Exchange Commission. No assurance can be given that such future results will be achieved. Such forward-looking statements contained in this document speak only as of the date of this press release. We expressly disclaim any obligation or undertaking to update these forward-looking statements contained in this press release to reflect any change in our expectations or any change in events, conditions, or circumstances on which such statements are based unless required to do so by applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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