



IGM Biosciences Announces Expansion of IgM Platform into Infectious Diseases, Publication of Preclinical Data in *Nature* Demonstrating Engineered IgM Antibody Antiviral Activity for the Treatment and Prevention of COVID-19

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Company Expects to Advance First Intranasally Administered IgM Antibody, IGM-6268, into the Clinic in Third Quarter of 2021

MOUNTAIN VIEW, Calif., June 03, 2021 (GLOBE NEWSWIRE) -- [IGM Biosciences, Inc.](#) (Nasdaq: IGMS) a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies, today announced the expansion of its IgM antibody platform into infectious diseases, with the anticipated advancement of a new pipeline candidate, IGM-6268, into the clinic in the third quarter of 2021. IGM-6268 is an IgM version of an anti-SARS-CoV-2 IgG monoclonal antibody being developed as an intranasally administered agent for the treatment and prevention of COVID-19. The announcement coincides with the publication in *Nature* of an article entitled "Nasal delivery of an IgM offers broad protection from SARS-CoV-2 variants," which is available now [online](#) and will be published in a future print issue of *Nature*. The article describes results from preclinical studies demonstrating significantly greater neutralization of SARS-CoV-2 with an IgM antibody compared to IgG antibodies, the potent neutralization of all evaluated mutant Variants of Concern (VoC) and Variants of Interest (VoI), and the ability to provide effective preventative and therapeutic protection when delivered intranasally in mice. The work described in the paper was performed in collaboration with The University of Texas Medical Branch at Galveston (UTMB), and The University of Texas Health Science Center at Houston (UTHealth). IGM has exclusively licensed the rights to the antibodies used to generate IGM-6268 and related intellectual property from the University of Texas System.

"High viral load in the respiratory tract correlates with severe illness and mortality in patients with COVID-19," said Dr. Zhiqiang An, Director of the UTHealth Texas Therapeutics Institute, Professor of Molecular Medicine at McGovern Medical School at UTHealth, and one of the corresponding authors on the publication. "Respiratory mucosal antibodies are key to clearing SARS-CoV-2 infection and reducing viral transmission and IgM antibodies are nature's first line of defense against pathogens such as viruses. The current EUA antibodies, which are all IgG antibodies, are administered intravenously at high doses and don't directly target the main sites of infection. Moreover, SARS-CoV-2 has evolved mutations that severely compromise the neutralizing activities of multiple IgG monoclonal antibodies, including those under clinical trials and authorized for emergency use. Therefore, developing new antibody therapies that can overcome these challenges is an urgent unmet need, and we are pleased with the data published today."

Results from the study published in *Nature* found that, among the anti-SARS-CoV-2 IgG, IgA, and IgM antibodies screened, IgM antibodies were in all cases significantly more potent than IgG and IgA antibodies in neutralizing virus. IGM-6268, described as IgM-14 in the publication, was shown to be effective for prophylaxis and treatment in animal models when administered intranasally, and also demonstrated significantly increased potency against wild type SARS-CoV-2 and emerging natural viral variants, such as the current UK, South African and Brazilian VoC strains, Vols, as well as the antibody escape mutants for the current Emergency Use Authorized antibodies.

"The ability to transform IgG antibodies into potently neutralizing IgM antibodies for the possible prevention and treatment of COVID-19 with broad coverage of VoCs, Vols and viral escape mutants is a very exciting application of our IgM platform that could address an urgent unmet medical need," said Fred Schwarzer, CEO of IGM Biosciences. "We look forward to advancing IGM-6268 as quickly as possible and plan to initiate a clinical study in the third quarter of this year, marking the expansion of our IgM antibody platform from oncology into infectious diseases. We are grateful to our collaborators at UTMB and UTHealth and our scientists at IGM for the exceptional work described in *Nature* today."

About IGM-6268

IGM-6268, an engineered human IgM monoclonal antibody designed for the treatment and prevention of COVID-19, has been shown in preclinical studies to be highly effective in preventing and treating COVID-19 after intranasal administration. Due to its ability to bind to SARS-CoV-2 with greater strength, IGM-6268 offers advantages over current IgG treatments, including 100x to 1,000x greater neutralizing potency than comparable IgG antibodies, and the ability to effectively neutralize Variants of Concern and Variants of Interest. In our *in vivo* models, IGM-6286 appeared to be well-tolerated, did not appear to present any adverse safety signals, and demonstrated good persistence in the sinus following intranasal administration.

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-6268, the Company's IgM technology platform and its expansion into infectious diseases, statements regarding the timing of the Company's planned clinical trials of IGM-6268, the Company's development strategy for IGM-6268, and statements by Dr. An and Mr. Schwarzer. 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 IGM-6268; IGM's ability to successfully and timely advance IGM-6268 through clinical studies; the risk that all necessary regulatory approvals cannot be obtained; IGM's ability to enroll patients in clinical studies; the potential for the results of clinical studies of IGM-6268 to differ from preclinical, preliminary or expected results; the risk that IGM-6268 may cause significant adverse events, toxicities or other undesirable side effects; the risk that initial, interim, topline or preliminary data from IGM's clinical studies 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 IGM-6268 for clinical studies; 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 studies, enrollment in its current and future clinical studies and progression of its collaborations and related efforts; the potential market for IGM-6268, 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, licenses or agreements 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 collaborations, licenses or agreements; 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 May 6, 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.

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