I-Mab Submits IND Application to Initiate Study of TJM2 for Treatment of Cytokine Storm Associated with Severe COVID-19 in South Korea

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-The clinical study will explore the potential of TJM2, an anti-GM-CSF monoclonal antibody, to treat cytokine release syndrome in severe and critically ill patients with coronavirus disease

-Submission follows the announcement of plans to develop TJM2 in the U.S. for the same indication

SHANGHAI, China, and ROCKVILLE, MD., March 30, 2020 (GLOBE NEWSWIRE) -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of novel or highly differentiated biologics to treat diseases with significant unmet medical needs, particularly cancers and autoimmune disorders, today announced that it has submitted an Investigational New Drug (IND) application to South Korea's Ministry of Food and Drug Safety (MFDS), to evaluate the safety and efficacy of TJM2 in treating cytokine storm (CS) in severe and critically ill patients caused by the coronavirus disease (COVID-19). TJM2 is an I-Mab-discovered neutralizing antibody against human granulocyte-macrophage colony stimulating factor (GM-CSF), an important cytokine that plays a critical role in acute and chronic inflammation. The IND submission follows the announcement on March 13, 2020 of a similar program initiated by I-Mab in the U.S.

The proposed clinical trial in South Korea is a single-arm, open-label pilot study that will evaluate the effects of TJM2 on reducing cytokine levels, including GM-CSF, in patients with severe COVID-19 disease.

GM-CSF levels increase in the plasma of COVID-19 patients suffering from CS. CS is an overreaction of the immune system associated with significant clinical complications in severe and critically-ill patients infected by SARS-CoV-2[1] [2], it also occurs in CAR-T therapy as a severe side effect [3].

"We have moved to quickly expand clinical development of TJM2 in this patient population to South Korea after recently initiating development in the United States, and we are deploying all necessary resources to support these projects to help address this urgent global health crisis," said Dr. Joan Shen, CEO of I-Mab. "Recent data, including safety, pharmacokinetic (PK) and pharmacodynamic (PD) results generated from a previous single ascending dose study, preclinical studies, and research by the medical and scientific community studying COVID-19-associated CS will provide science-based rationale and solid evidence to help us further explore the potential of TJM2 as an innovative treatment for CS."

The Company has successfully completed a Phase I single ascending dose study of TJM2 in the United States (NCT03794180), in which TJM2 exhibited favorable safety, tolerability, PK/PD, and immunogenicity profiles. TJM2 also received IND clearance from China's National Medical Products Administration for a multiple-dose Phase 1b study in patients with rheumatoid arthritis (RA). The results from the planned COVID-19 CS study will also be used to further evaluate the potential therapeutic role of TJM2 in reducing or preventing CS and neurotoxicity associated with CAR-T therapy.

According to the WHO, as of March 29, 2020, there were more than 634,835 confirmed cases and more than 29,957 deaths related to SARS-CoV-2 infection globally. Severe and critically ill patients account for approximately 20% of all diagnosed patients.

[1]. Huang C, Wang Y, Li X et al. (2020) Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet 2020 Jan 24. pii: S0140-6736(20)30183-5.

[2]. Wu Z, McGoogan JM (2020) Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. JAMA 2020 Feb 24. doi:10.1001/jama.2020.2648

[3]. Shimabukuro-Vornhagen A, Gödel P, Subklewe M et al. (2018) Cytokine release syndrome. Journal for ImmunoTherapy of Cancer (2018) 6:56. doi.org/10.1186/s40425-018-0343-9

About TJM2

TJM2 is an internally discovered neutralizing antibody against human GM-CSF, an important cytokine that plays a critical role in chronic inflammation and destruction in autoimmune diseases such as RA. GM-CSF can polarize macrophages into the pro-inflammatory M1 phenotype and is known to induce an inflammatory cascade involving other pro-inflammatory cytokines such as tumor-necrosis factor (TNF), interleukin-1 (IL-1), IL-6, IL-12, and IL-23. It is evident that GM-CSF plays a crucial role in the pathogenesis and disease progression of multiple autoimmune conditions.

TJM2 specifically binds to human GM-CSF with high affinity and can block GM-CSF from binding to its receptor, thereby preventing downstream signaling and target cell activation. As a result, it can effectively inhibit inflammatory responses mediated by macrophages, neutrophils, and dendritic cells, leading to reduced tissue inflammation and damage.

TJM2 is expected to be the first antibody of its class to enter clinic trials in China in 2020.

About I-Mab

I-Mab (Nasdaq: IMAB) is a dynamic, global biotech company exclusively focused on developing novel or highly differentiated biologics in the therapeutic areas of immuno-oncology and autoimmune diseases. I-Mab's mission is to bring transformational medicines to patients through innovation. I-Mab's innovative pipeline of more than 10 clinical and pre-clinical stage drug candidates is driven by the Company's Fast-to-PoC (Proof-of-Concept) and Fast-to-Market development strategies through internal R&D and global partnerships. The Company is on track to become a fully integrated end-to-end global biopharmaceutical company with cutting-edge discovery platforms, proven pre-clinical and clinical development expertise, and world-class GMP manufacturing capabilities. I-Mab has offices in China and the United States. For more information, please visit http://ir.i-mabbiopharma.com

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This press release contains statements that may constitute "forward-looking" statements pursuant to the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as "will," "expects," "anticipates," "aims," "future," "intends," "plans," "believes," "estimates," "likely to" and similar statements. Statements that are not historical facts, including statements about I-Mab's beliefs, plans and expectations, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties. Further information regarding these and other risks is included in I-Mab's filings with the SEC. All information provided in this press release is as of the date of this press release, and I-Mab does not undertake any obligation to update any forward-looking statement, except as required under applicable law.

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