I-Mab Reports Interim Results from Part 1 Study for Anti-GM-CSF Antibody TJM2 to Treat COVID-19 Patients with -Cytokine Release Syndrome

5月 27, 2020

- Though blinded, there is a trend for correlation between clinical improvement and reduced levels of some disease related cytokines

- Data monitoring committee (DMC) reviewed the clinical data and unanimously recommended proceeding to part 2 of the study and endorsed the change of low dose treatment arm (3mg/kg) to high dose (6mg/kg)

- To preserve the original clinical trial design with data blinding and integrity, the clinical efficacy data will be revealed upon completing part 2 of the study

- I-Mab to host a conference call to discuss the latest updates on Thursday, May 28, 2020, 8:30 a.m. ET.

SHANGHAI and GAITHERSBURG, MD, May 27, 2020 /PRNewswire/ -- I-Mab (NASDAQ: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development and commercialization of novel biologics, today announced interim results from a multi-center, double blinded, randomized, placebo-controlled, three-arm clinical study (NCT04341116) of TJM2 in patients with cytokine release syndrome (CRS) associated with severe coronavirus disease 2019 (COVID-19).

TJM2, also known as TJ003234, 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 tissue inflammation. This study adopts a robust clinical trial design and represents one of the first double-blind, placebo-controlled and randomized studies to evaluate the therapeutic role of anti-GM-CSF antibody in severe COVID-19 patients. I-Mab has followed a rigorous and robust clinical trial protocol, the first among similar anti-GM-CSF antibody studies globally, to ensure robustness of the study conclusion and data integrity.

"I-Mab's carefully planned clinical trial of its novel anti-GM-CSF agent brings potential new hope to effectively treat severe SARS-CoV-2 infection by suppressing uncontrolled inflammation", said Dr. Marcel Curlin, M.D., Associate Professor, Department of Medicine, Division of Infectious Diseases, Oregon Health and Sciences University. "Preliminary results and positive review from the DMC are encouraging, and if we now begin to see an efficacy signal, we will have a powerful new approach to treating severe disease due to COVID-19."

Dr. Jingwu Zang, M.D., Ph.D., Founder and Honorary Chairman and Director of I-Mab said, "As an innovative global biotech company, I-Mab has a responsibility to help address the urgent global health crisis. Since the outbreak took place, we sprang into action to prioritize TJM2 in response to the urgent medical needs. It is clear that the rationale and expectation of our study is further supported by the preliminary and encouraging evidence from other pilot studies with GM-CSF antibody class for this clinical indication."

Part 1 of the study evaluated the safety and tolerability of TJM2 in a total of 24 patients who were randomized at a ratio of 1:1:1 to receive either a single dose of 3 mg/kg TJM2, a single dose of 6 mg/kg TJM2 or placebo (standard care), administered by intravenous (IV) infusion. Data from Part 1 of the study were reviewed by a DMC to assess patient safety and overall conduct of the study. After comprehensive review and analysis, the DMC concluded that I-Mab can commence the Part 2 of the study as planned, indicating TJM2 is safe and well-tolerated in the severe COVID-19 patients in the study. The DMC also endorsed protocol changes, including broadening the inclusion criteria and dosing all patients at 6 mg/kg of TJM2 or placebo.

Part 2 of the study with a similar design to Part 1 will target the same patient population and is expected to be initiated shortly. It will evaluate the efficacy, safety and cytokine levels following a single dose of 6mg/kg TJM2 or placebo in 120 patients with severe COVID-19.

"We appreciate DMC's assessment and positive recommendation which is a testament to I-Mab's science-focused clinical development capabilities," said Dr. Joan Shen, MD, PhD, CEO of I-Mab. "We are committed to conducting a robust clinical trial to the highest standards and we believe we have the most advanced anti-GM-CSF study in COVID-19 that could potentially lead to registration of TJM2 in the U.S. The DMC's confirmation of TJM2's safety profile bolsters the drug's potential to address the complications among the severe and critically ill – and ultimately save lives."

The emerging data indicate that the common features among COVID-19 patients particularly those severely or critically ill include lymphopenia and significantly elevated serum levels of pro-inflammatory cytokines including GM-CSF and IL-6, IFN-gamma[1] [2]. Moreover, recently published data indicate that COVID-19 can induce a cytokine storm instigated by extensive immune cell infiltration and the release of GM-CSF and IL-6[3]. These inflammatory cytokines drive aberrant activation of monocytes and lymphocytes which in turn provoke increased production of more cytokines and chemokines in a feed forward cycle, resulting in the cytokine storm, or CRS, severe pulmonary complications and mortality. Therefore, blocking of GM-CSF by TJM2 may impact the upstream of cytokine storm network to prevent or curb the hyperinflammation and immunopathology which may be responsible for the complications associated with severe COVID-19.

According to the WHO, as of May 26, 2020, there were 5,404,512 confirmed cases and 343,514 deaths of COVID-19 globally. Severe and critically ill patients account for approximately 20% of all diagnosed patients.

I-Mab Conference Call and Webcast Information

Investors and analysts are invited to join the conference call on Thursday, May 28, 2020 at 8:30 a.m. ET using the following dial-in information:

U.S.: +1 646 722 4977 (toll) or +1 855 824 5644 (toll free)
Mainland China: 400 821 0637 (toll) or 800 988 0563 (toll free)
Hong Kong: +852 3027 6500 (toll)
PIN: 94796283#

A live webcast and an archived replay of the conference call can be accessed on the Company's investor relations website at http://ir.i-mabbiopharma.com

[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] Zhou Y, Fu B, Zheng X, et al. Aberrant pathogenic GM-CSF+ T cells and inflammatory CD14+CD16+ monocytes in severe pulmonary syndrome patients of a new coronavirus. Pre-Print. 2020.

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 biologics of novel or highly differentiated in the therapeutic areas of immuno-oncology and autoimmune diseases. Company'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 preclinical and clinical development expertise, and world-class GMP manufacturing capabilities. I-Mab has offices in Beijing, Shanghai, Hong Kong and Maryland, United States. For more information, please visit http://ir.i-mabbiopharma.com

Forward Looking Statements

This press release includes certain disclosures which contain "forward-looking statements." You can identify forward-looking statements because they contain words such as "anticipate" and "expected." Forward-looking statements are based on I-Mab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in filings with the U.S. Securities and Exchange Commission. I-Mab undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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