I-Mab Announces IND Clearance from FDA for TJM2 to Treat Cytokine Release Syndrome (CRS) Associated with Severe Coronavirus Disease 19 (COVID-19)

4月 3, 2020

SHANGHAI, China and ROCKVILLE, MD., April 03, 2020 (GLOBE NEWSWIRE) -- I-Mab (Nasdaq: IMAB) (the “Company”), 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, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug application (IND) to initiate clinical study for TJM2 to treat cytokine release syndrome (CRS) associated with severe illness caused by the coronavirus disease 2019 (COVID-19). The Company has also obtained central institutional review board (IRB) approval from the Western Institutional Review Board on the same day. 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 inflammation.

Upon the FDA IND clearance, the Company may proceed with the study in the United States. The proposed clinical trial is a multi-center, randomized, double-blind, placebo-controlled, three-arm study to evaluate the safety, tolerability and efficacy of TJM2 in reducing the severity of complications as well as levels of multiple cytokines in patients with severe COVID-19.

“With the IND approval, we will be able to rapidly explore the potential of TJM2 in preventing and treating CRS associated with COVID-19 and help address the immediate needs of the significant numbers of patients becoming severe in the current pandemic,” said Dr. Joan Shen, CEO of I-Mab. “We are preparing for clinical trial initiation in the U.S. as soon as possible in order to join the fight against COVID-19 with our proprietary drug, in hope of reducing the morbidity and mortality caused by this illness.”

I-Mab has plans to expand the study into other hard-hit countries. On March 30, 2020, I-Mab announced submission of 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 CRS in severe COVID-19 patients in South Korea.

The results from the planned study in the United States will also be used to further evaluate the potential therapeutic role of TJM2 in reducing or preventing cytokine storm and neurotoxicity associated with CAR-T therapy.

According to the WHO, as of April 2, 2020, there were more than 896,450 confirmed cases and more than 45,526 deaths related to SARS-CoV-2 infection globally. Severe and critically ill patients account for approximately 20% of all diagnosed patients.

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

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.

For more information, please contact:

I-Mab

Jielun Zhu, CFO
E-mail: jielun.zhu@i-mabbiopharma.com
Office line: +86 21 6057 8000

Claire Xu, Head of U.S. Site
Email: claire.xu@i-mabbiopharma.com
Office line: +1 240 767 6981

Investor Inquiries:

Burns McClellan, Inc. (Americas and Europe)
Steve Klass
E-mail: sklass@burnsmc.com
Office line: +1 212 213 0006

The Piacente Group, Inc. (Asia)
Emilie Wu
E-mail: emilie@thepiacentegroup.com
Office line: + 86 21 6039 8363

Media Inquiries:

Burns McClellan, Inc.
Ryo Imai / Robert Flamm, Ph.D.
E-mail: rimai@burnsmc.com / rflamm@burnsmc.com
Office line: +1 212 213 0006