I-Mab Announces First Patient Dosed in Phase 1b Study of Plonmarlimab in Rheumatoid Arthritis in China

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SHANGHAI and GAITHERSBERG, Md., Aug. 17, 2020 /PRNewswire/ -- I-Mab (the "Company") (Nasdaq: IMAB), a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of novel biologics, today announced that the first patient has been dosed with plonmarlimab (also known as TJM2) in a Phase 1b study (CXSL1900100; NCT04457856) to evaluate its use in treating patients with rheumatoid arthritis (RA) in China.

Plonmarlimab is a humanized immunoglobulin G1 (IgG1) antibody that targets the cytokine granulocyte-macrophage colony-stimulating factor (GM-CSF), which plays a critical role in autoimmune and inflammatory disease. Neutralization of GM-CSF can dampen inflammatory responses and may provide clinical benefits to patients with autoimmune conditions such as RA.

"Studies have shown that GM-CSF has a profound role in modulating immune response and suppressing autoimmune diseases. We are eager to further investigate and characterize the safety and efficacy profile of plonmarlimab in treating patients with RA, a disease that continues to afflict five million people in China today[1]," said Prof. Zhan-Guo Li, lead investigator of the trial and Chief of the Department of Rheumatology and Immunology at Peking University Health Science Center.

The Phase 1b trial is a multi-center, double-blind, placebo-controlled study with 63 patients who will receive a single dose or multiple doses of the treatment for up to eight weeks. It is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and immunogenicity of plonmarlimab in patients with RA. I-Mab has successfully completed a first-in-human single ascending dose study of plonmarlimab in healthy volunteers in the United States (NCT03794180). A Phase 2 trial to treat patients with cytokine release syndrome associated with COVID-19 is currently in progress in the US.

"Plonmarlimab is the first antibody of its class entering clinical trials in China. We believe it has the great potential to become a new treatment option as a disease-modifying anti-rheumatic agent. Our intention is to achieve proof of concept in RA and expand to broad autoimmune diseases with unmet needs," said Dr. Joan Shen, Chief Executive Officer, I-Mab.

[1] Wenhui Xie, X. Y. (2019). The plight and light of treating rheumatoid arthritis in China. The Lancet Rheumatology, 1(2), E81-E82.

About Plonmarlimab (TJM2)

Plonmarlimab 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. Plonmarlimab 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.

About I-Mab

I-Mab (Nasdaq: IMAB) is a dynamic, global biotech company exclusively focused on discovery, development and soon commercialization of novel or highly differentiated biologics in the therapeutic areas of immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational medicines to patients around the world 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 transitioning from a clinical stage biotech company toward a fully integrated global biopharmaceutical company with cutting-edge R&D capabilities, world-class GMP manufacturing facility and commercial capability. 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 contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding data from the plonmarlimab (TJM2) China Phase 1b trial of rheumatoid arthritis, the potential implications of clinical data for patients, and I-Mab's advancement of, and anticipated clinical development, regulatory milestones and commercialization of plonmarlimab (TJM2). Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including but not limited to I-Mab's ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or NDA/BLA approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of I-Mab's drug candidates; I-Mab's ability to achieve commercial success for its drug candidates,

if approved; I-Mab's ability to obtain and maintain protection of intellectual property for its technology and drugs; I-Mab's reliance on third parties to conduct drug development, manufacturing and other services; I-Mab's limited operating history and I-Mab's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; and the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, as well as those risks more fully discussed in the "Risk Factors" section in I-Mab's most recent annual report on Form 20-F, as well as discussions of potential risks, uncertainties, and other important factors in I-Mab's subsequent filings with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to I-Mab, and 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

Gigi Feng, Vice President and Global Head of Corporate Communications
Email: gigi.feng@i-mabbiopharma.com
Office line: +86 21 6057 8000

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

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