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I-Mab to kick off clinical trials for monoclonal antibody TJM2 in China

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TJM2 is a humanized immunoglobulin G1 (IgG1) neutralizing antibody targeting the cytokine granulocyte-macrophage colony-stimulating factor (GM-CSF) with the potential to treat patients with autoimmune and inflammatory diseases

I-Mab Biopharma ("I-Mab"), a China and U.S.-based clinical-stage biopharmaceutical company exclusively focused on the discovery and development of novel or highly differentiated biologics in immuno-oncology and autoimmune diseases have announced that National Medical Products Administration (NMPA) approved its IND application for TJM2 to conduct clinical trials in patients with rheumatoid arthritis (RA). TJM2 is a humanized immunoglobulin G1 (IgG1) neutralizing antibody targeting the cytokine granulocyte-macrophage colony-stimulating factor (GM-CSF) with the potential to treat patients with autoimmune and inflammatory diseases in which GM-CSF plays a critical role.

TJM2 is the first in-house developed drug candidate from I-Mab's global portfolio of internally developed candidates to have entered clinical trials. Earlier this year, I-Mab conducted a first-in-human phase 1 clinical trial with TJM2 in healthy volunteers in the U.S. (NCT03794180). Having successfully completed that trial, I-Mab filed an IND with the NMPA for TJM2 in patients with RA and, subsequently, received regulatory clearance on November 8. The current phase I study is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and immunogenicity of TJM2 in patients with RA.

"We believe TJM2 has broad potential for the treatment of patients with autoimmune and inflammatory diseases and are pleased to have obtained clearance from the Chinese health authorities to continue further clinical development of TJM2 in RA patients in China," said Jingwu Zang, MD., PhD., Founder and Honorary Chairman of I-Mab Biopharma. "This is an important milestone for I-Mab and demonstrates our ability to conduct clinical trials in both the U.S. and China and leverage data between the countries to expedite our clinical development programs in our goal to bring innovative products to the patients."