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I-Mab gets UDFDA IND nod for exclusive monoclonal antibody TJM2

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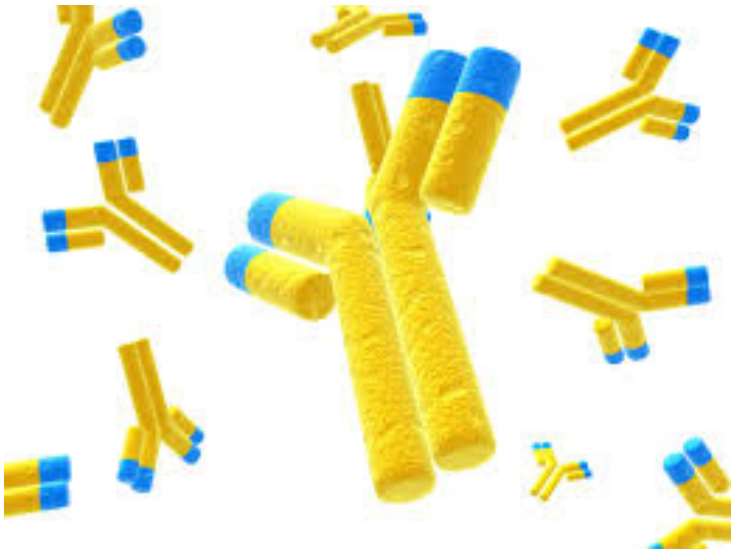
The first I-Mab proprietary drug candidate to enter clinical trials in the United State



I-Mab Biopharma (I-Mab), a China-based clinical-stage biopharmaceutical company exclusively focused on the development of innovative biologics in immuno-oncology and autoimmune diseases, today announces that the US Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application for TJM2, a humanized immunoglobulin G1 (IgG1) targeting granulocyte-macrophage-colony-stimulating factor (GM-CSF), with the best-in-class potential to treat autoimmune and inflammatory diseases.

TJM2 is the first candidate from I-Mab's innovative proprietary pipeline to be approved for clinical trials by the FDA. GM-CSF is a critical pro-inflammatory cytokine that plays a pivotal role in tissue inflammation and destruction in autoimmune and inflammatory diseases. TJM2 will be tested in clinical trials for its potential as a new treatment option for diseases such as rheumatoid arthritis and osteoarthritis.

"We are delighted to receive this IND approval from the FDA to start clinical studies with TJM2 in the United States. This is another important milestone for I-Mab's global strategy and a strong testament to I-Mab's in-house research capability to develop highly innovative biologics for patients around the world," said Jingwu Zang, CEO of I-Mab.

The initial first-in-human (FIH) single dose study will look at safety, tolerability, pharmacokinetics/pharmacodynamics and immunogenicity of TJM2 in healthy volunteers (including Chinese subjects) in the United States.