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I-Mab receives FDA orphan drug designation for cancer drug

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I-Mab receives FDA orphan drug designation for its novel Claudin 18.2 x 4-1BB bispecific antibody TJ-CD4B for the treatment of gastric cancer



China based I-Mab, a clinical-stage biopharmaceutical company committed to the discovery, development, and commercialization of novel biologics, has announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for TJ-CD4B, a novel Claudin 18.2 x 4-1BB bispecific antibody, for the treatment of gastric cancer including cancer of gastroesophageal junction.

TJ-CD4B is the first clinical-stage bispecific antibody that binds to Claudin 18.2 (CLDN18.2)-expressing cancer cells and co-stimulatory molecule 4-1BB on T cells to exert a tumor-killing effect. Unlike other therapies involving CLDN18.2, TJ-CD4B has a broader anti-tumor effect covering cancers expressing low levels of CLDN18.2. Preclinical studies have suggested that TJ-CD4B is superior to current CLDN18.2 antibodies and 4-1BB agonistic antibodies due to its stronger anti-tumor activity and a minimal 4-1BB related systemic toxicity.

TJ-CD4B is part of I-Mab's highly innovative bispecific antibody pipeline. It is currently undergoing phase 1 clinical trials (NCT04900818) both in the U.S. and China in patients with advanced solid tumors, including gastric cancer, gastroesophageal junction carcinoma, esophageal adenocarcinoma, and pancreatic ductal carcinoma. I-Mab has made significant progress in the global clinical development of TJ-CD4B. In the ongoing dose-escalation study, TJ-CD4B was safe and well-tolerated at dose up to 3 mg/kg weekly. The company plans to advance the study in biomarker-selected population subsequently.