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I-Mab Biopharma commences pivotal study of TJ202/MOR202 in China

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I-Mab Biopharma ("I-Mab"), a global biopharmaceutical company based in China and the United States and focused on the discovery and development of novel or highly differentiated biologics in immuno-oncology and autoimmune diseases has announced the dosing of the first patient in mainland China in its registrational study evaluating its human CD38 antibody (TJ202/MOR202) in patients with relapsed or refractory multiple myeloma (MM).

I-Mab initiated two registrational trials with TJ202/MOR202 in relapsed or refractory MM in Taiwan in early 2019 and expanded these trials into mainland China in late 2019, after receiving IND clearance from the National Medical Products Administration (NMPA). The first trial (NCT03860038), a Phase 2 trial, is designed to evaluate the efficacy and safety of TJ202/MOR202 as a third-line treatment in patients with relapsed or refractory MM, while the second trial (NCT03952091) is assessing the efficacy and safety of the combination of TJ202/MOR202 plus lenalidomide (LEN) and dexamethasone (DEX) versus the combination of LEN and DEX in patients with relapsed or refractory MM who received at least one prior line of treatment. Site preparations in China have proceeded well with the first patient being dosed on schedule in the Phase 2 study. Under I-Mab's fast-to-market development strategy, both studies have been designed as pivotal trials, which, if successful, could pave the way for new drug applications (NDA) for TJ202/MOR202 in Greater China.

"We are pleased that the first patient has been successfully dosed in mainland China," said Jingwu Zang, MD., PhD., Founder and Honorary Chairman of I-Mab Biopharma. "The initiation of enrollment in China of TJ202/MOR202 is an important milestone. We look forward to accelerating TJ202/MOR202 clinical program significantly towards registration, which will benefit the patients with multiple myeloma in China," added Dr. Zang.

TJ202/MOR202 is a differentiated antibody originally developed by MorphoSys AG that has shown promise in preclinical animal studies and early human clinical trials. I-Mab licensed the product from MorphoSys and owns the exclusive rights for its development and commercialization in mainland China, Hong Kong, Macao and Taiwan. I-Mab is developing this product in multiple myeloma and in certain autoimmune diseases, including systemic lupus erythematosus.