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Bridge Biotherapeutics announces CNMPA clearance of IND for BBT-401

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The Phase I clinical study in China will be initiated in May 2020

Bridge Biotherapeutics Inc. a clinical stage biotech company headquartered in Seongnam, Republic of Korea has announced that the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) cleared the Investigational New Drug (IND) application submitted as of September 25, 2019 for BBT-401, a potent first-in-class Pellino-1 inhibitor for the treatment of ulcerative colitis (UC).

Bridge Biotherapeutics plans to initiate a Phase I study of BBT-401 in Chinese subjects in May 2020. The safety, tolerability and pharmacokinetic data of the drug candidate will be assessed with single and multiple ascending oral doses in the study. The study will include 30 healthy volunteers and is targeting to complete by end of 2020.

The company entered a partnership with Daewoong Pharmaceutical to jointly develop BBT-401, under the license and co-development agreement signed in December 2018. Daewoong Pharmaceutical acquired the exclusive right for the development and commercialization of BBT-401 in 22 Asian countries, including China, Japan and Korea. The two companies have been closely collaborating on the clinical development for BBT-401 in Asian countries, preceded by the Phase II study in the U.S. with active UC patients.

BBT-401, discovered by SKKU (Sungkyunkwan University) and KRICT (Korea Research Institute of Chemical Technology) is a GI-tract restricted small molecule inhibitor of Pellino-1. From the Phase I study, the drug candidate was proved to be well tolerated and safe in humans with local distribution in colon. The drug candidate in now on its Phase II study in selected groups of active patients with UC in the U.S.