

Bridge Bio announces activation of clinical trial sites for Phase 2 study of UC drug candidate

28 December 2018 | News

Three study sites located in California, Maryland and North Carolina have been activated and the patient participants enrollment is now underway.



Bridge Biotherapeutics Inc, a clinical stage biotech company headquartered in Seongnam, South Korea has announced that the company has successfully activated clinical study sites for the Phase 2 study of BBT-401, a drug candidate for Ulcerative Colitis (UC) treatment.

The Phase 2 clinical study is a multi-center, randomized, double-blind, placebo-controlled study for evaluating the efficacy and safety of BBT-401 in groups of patients with active UC. The primary endpoint of the study will be the change from baseline in total Mayo Score at Week 8.

Three study sites located in California, Maryland and North Carolina have been activated and the patient participants enrollment is now underway. Bridge Biotherapeutics anticipates that seven study sites will be additionally initiated by early next year and dosing and clinical data analysis in the first out of three cohorts will be finalized by the second half year of 2019. The dose escalation of the second and the third cohorts will be determined based on the results of previous cohorts.

"We are very excited to initiate the Phase 2 study following the successful first-in-human study and Team Bridge will continue to commit to developing beneficial treatments for patients with UC and the site activation for the Phase 2 study is a crucial stepping stone for the goal," stated Dr. Gwang-hee Lee, the Head of Translational Research at Bridge Biotherapeutics.

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. Bridge Biotherapeutics and Daewoong Pharmaceutical Co., Ltd., a Korean pharmaceutical giant, have recently signed a license agreement for co-development of BBT-401 in Asian countries.