

Bridge Biotherapeutics gets FDA ODD for BBT-877

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South Korea based Bridge Biotherapeutics Inc., a clinical stage biotech company announced that the U.S. Food and Drug Administration (FDA) has granted an orphan drug designation (ODD) to BBT-877, a drug candidate under development for Idiopathic Pulmonary Fibrosis (IPF) treatment.

BBT-877, a potent best-in-class Autotaxin (ATX) inhibitor deregulates ATX, the enzyme found to be engaging in inflammation and fibrosis by generating the lipid signaling molecule. The early-stage compound of BBT-877 had been originally discovered by LegoChem Biosciences and has been under the development process by the lead of Bridge Biotherapeutics since the company acquired the worldwide exclusive right for further developments in 2017.

In August 2018, Bridge Biotherapeutics presented the results of the preclinical study on BBT-877 at the IPF Summit, attracting pulmonologists' interest on the efficacy and safety of the drug candidate. The data has demonstrated the best-in-class opportunity in comparison to a current development pipeline compound.

Bridge Biotherapeutics will commence a Phase 1 study of BBT-877 in the U.S. next month to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of the drug candidate in healthy volunteers. The planned study will be performed in two phases, a Single Ascending Dose (SAD) phase with 5 cohorts and a Multi Ascending Dose (MAD) phase with 3 cohorts. The estimated primary completion date is currently expected in late 2019.