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Bridge Biotherapeutics files Investigational NDA for NSCLC drug

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The targeted cancer therapy showed a potential of activity against EGFR C797S mutation in pre-clinical studies

Bridge Biotherapeutics Inc., a clinical stage biotech company headquartered in Seongnam, South Korea, announced that the company filed an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) and the Ministry of Food and Drug Safety (MFDS) in Korea to initiate phase I/II study of BBT-176, a clinical candidate of targeted lung cancer therapy.

BBT-176, a novel epidermal growth factor receptor - tyrosine kinase inhibitor (EGFR-TKI) is designed to inhibit EGFR with C797S mutations, which arise as Tagrisso (osimertinib) resistant mutations following Tagrisso treatment in non-small cell lung cancer (NSCLC). BBT-176 exhibited strong antitumor efficacy in xenograft models harboring C797S triple mutations including Del19/T790M/C797S and L858R/T790M/C797S. Furthermore, BBT-176 displayed markedly enhanced efficacy when combined with anti-EGFR antibodies.

Since the EGFR C797S mutation was reported 3 years ago, as the first evidence of Tagrisso resistance, no major breakthroughs have been achieved to target the clinically relevant mutant variant that impedes covalent bond formation with irreversible EGFR inhibitors.[i]

The company plans to initiate dose escalation studies in advanced NSCLC patients in Korea next year and to develop further clinical studies in both Korea and the US afterwards. In the Phase I/II study with NSCLC patients, the safety, tolerability and efficacy of the candidate will be observed.

"We are proud of the IND submission for BBT-176, which has shown a potential to be developed as a highly mutant-selective, fourth-generation EGFR-TKI for NSCLC treatment," stated James Lee, CEO of Bridge Biotherapeutics. "Our team will make our best effort to develop novel targeted lung cancer therapy inhibiting C797S EGFR mutation."

BBT-176 was discovered by Korea Research Institute of Chemical Technology (KRICT), a Korean government research institute, and was licensed to Bridge Biotherapeutics in December 2018 for the worldwide exclusive right for further development.