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Bridge Biotherapeutics gets FDA IND clearance for lung cancer drug

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Bridge Biotherapeutics will initiate a dose escalation study as the first part of the phase I/II study in Korea to find the maximum tolerated dose (MTD) and to observe safety, tolerability and anti-tumor efficacy of BBT-176 in the patient groups of advanced NSCLC



Bridge Biotherapeutics Inc., a clinical stage biotech company headquartered in Seongnam, Republic of Korea, announced that the Investigational New Drug (IND) application submitted to the U.S. Food and Drug Administration (FDA) has been cleared on January 18th.

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). In the pre-clinical studies, BBT-176 exhibited strong anti-tumor efficacy in C797S triple mutations. Furthermore, BBT-176 displayed markedly enhanced efficacy when combined with anti-EGFR antibodies.

Bridge Biotherapeutics will initiate a dose escalation study as the first part of the phase I/II study in Korea to find the maximum tolerated dose (MTD) and to observe safety, tolerability and anti-tumor efficacy of BBT-176 in the patient groups of advanced NSCLC. In the second part of the study, which will be a dose expansion study, the safety, tolerability and efficacy along with the best MTD of the drug candidate will be assessed in the U.S. and Korea.

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.

Lung cancer is the leading cause of cancer death, accounting for about one-fifth of all cancer deaths. It is split into NSCLC and small cell lung cancer (SCLC) and NSCLC accounts for approximately 85% of all lung cancers. Overall, across 8 major countries including the U.S., 5 EU countries, China and Japan, the total NSCLC population as of 2015 is assumed 2 million and the incidence of NSCLC is expected to increase at an annual growth rate of 3.1% from 2015 to 2025.