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China approves first and only therapy available for patients with EGFR Exon20 Insertion+ NSCLC

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EXKIVITY is the first category-1 innovative drug approved for Takeda China following a Phase 2 global pivotal study

Japan headquatered Takeda's EXKIVITY (mobocertinib) has been approved by the National Medical Products Administration (NMPA) of China for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). The therapy is clinically proven effective in patients with insertion mutations in exon 20 of the growth factor receptor (EGFR) whose disease has progressed during or after platinum-based chemotherapy.

Awny Farajallah, Head of Oncology Affairs Takeda Global Physicians said “Precision medicines like EXKIVITY can fight hard-to-treat cancers. We are introducing EXKIVITY in China as Takeda's second lung cancer therapy."

Sean Shan, president of Takeda China said “EXKIVITY offers an oral therapy targeted at a population that has historically been underserved, and this approval takes us one step closer to defeating this complex and heterogeneous disease for patients in this region.”

Approval is based on results from the platinum-pretreated population in the EXKIVITY Phase 1/2 study, which consisted of 114 NSCLC patients with EGFR exon 20+ insertion who received platinum-based chemotherapy. EXKIVITY is a first-class oral tyrosine kinase inhibitor (TKI) specifically designed to selectively target insertional mutations in exon 20 of the epidermal growth factor receptor (EGFR).

EXKIVITY is currently approved in the United States, Great Britain, Switzerland, South Korea, Australia and China.