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FDA approves Boehringer's lung cancer drug Gilotrif

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Singapore: US FDA has approved Boehringer Ingelheim' Gilotrif (afatinib) tablets for oral use, as a new first-line (initial) treatment for patients with metastatic non-small cell lung cancer (NSCLC) with common epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test.

Discovered and developed by Boehringer Ingelheim, the drug is the first FDA-approved oncology product from the company. In some people, genetic mutations lead to the constant activation of the EGFR protein, which is associated with uncontrolled cell division and the development and progression of NSCLC.

Among patients diagnosed with NSCLC (the most common form of lung cancer3), it is estimated that between 10 and 15 percent of Caucasians and approximately 40 percent of Asians have EGFR mutations4, which in 90 percent of cases are one of the two most common EGFR mutations (Del19 or L858R).

"The approval of Gilotrif offers a new treatment option and provides a personalized treatment approach for patients with EGFR mutation-positive metastatic non-small cell lung cancer," said Dr Berthold Greifenberg, vice president, Clinical Development and Medical Affairs, Oncology, Boehringer.

"Over the past decade, great progress has been made in understanding the biology of lung cancer and Gilotrif is an example of how, at BI, we are translating this knowledge into a new treatment option for patients."