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Pfizer cancer drug gets first-ever China SFDA nod

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Singapore: Pfizer received approval for Xalkori (crizotinib) for Chinese State Food and Drug Administration (SFDA), as the first-ever therapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) positive as detected by an SFDA-approved test.

Dr Wu Xiaobing, China country manager, Pfizer, "Xalkori is an important advancement in the treatment of this devastating illness, providing a new therapeutic option for the subset of patients afflicted with the disease. The speed, collaboration and critical focus of the XALKORI clinical development program reflect Pfizer's Personalized Therapy and Precision Medicine approaches to advancing our pipeline and strengthening our innovative core to deliver medicines that matter most."

Dr Jean CUI, lead inventor of Xalkori and a native of China, said that, "By better understanding the underlying genetic drivers of NSCLC, such as ALK, we can select patients who are more likely to respond to treatment, which increases the success rate of this personalized therapy. Xalkori represents a paradigm shift in NSCLC treatment, where we're moving away from a one-size-fits-all approach to biomarker-based treatment decisions. Xalkori truly serves as a good model for the future of drug development and cancer care."

The clinical trials' design for Xalkori required patients' tumors to prospectively test positive for the ALK fusion gene biomarker, increasing the likelihood of response to the treatment. This method, a first for a lung cancer therapy not yet on the market, allowed researchers to observe a strong efficacy signal in a selected patient population. In two multi-center single-arm clinical trials involving 255 patients with locally advanced or metastatic non-small ALK-positive NSCLC, objective response rates (ORR) of 51 percent and 61 percent were observed. Preliminary epidemiology suggests that approximately three-to-five percent of NSCLC tumors are ALK-positive, translating to approximately 28,000-to-46,000 NSCLC patients worldwide each year.

The development of Xalkori from publication of the discovery of the ALK fusion gene in NSCLC to US FDA approval in just four years, is a remarkable feat in the oncology world and reinforces the importance of collaboration among academic research, pharmaceutical, diagnostic and regulatory organizations.

The approval process of Xalkori in China, from the submission of the new drug application to the recent SFDA approval, took

only around 11 months, as part of its inclusion in the fast approval channel of the country's Center for Drug Evaluation (CDE). "The SFDA's quick decision highlights the Chinese government's commitment to accelerate the development of new therapies that address the unmet medical needs of patients," added Dr Xiaobing.

Professor Wu Yilong, director-elect of the Chinese Society of Clinical Oncology (CSCO), Chinese Anti-Cancer Association and Director of CSCO Cancer Biomarker Expert Panel, remarked that the approval of Xalkori underscores the important role of molecular biomarkers in cancer treatment. He said, "We strongly encourage lung cancer patients to talk to their oncologists about molecular tumor testing. By fully understanding the molecular biology of their tumor, patients and physicians can make the optimal personalized treatment decisions."

Xalkori has been approved by regulatory authorities in Japan, Korea, the EU, and other markets, since it was first approved by the US FDA in August 2011. With the SFDA's approval, it is estimated that Xalkori will be made available to patients in China in the middle of this year.