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FDA approves Pfizer's lung cancer drug

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Pfizer recently announced that the U.S. Food and Drug Administration (FDA) has aproved LORBRENA a third-generation anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor (TKI) for patients with ALK-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease; or whose disease has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. This represents the third FDA approval Pfizer has received for an oncology treatment, including two lung cancer medicines, within two months.

“Over the years, Pfizer has transformed research, management and treatment for patients with ALK-positive non-small cell lung cancer. Building upon our extensive understanding of tumor complexity and treatment resistance, LORBRENA was discovered by Pfizer scientists and developed specifically to inhibit tumor mutations that may drive resistance to other ALK tyrosine kinase inhibitors,” said Andy Schmeltz, Global President, Pfizer Oncology. “We believe that LORBRENA will benefit patients with ALK-positive metastatic non-small cell lung cancer that have progressed on prior therapy and continue to deliver on our commitment to addressing unmet needs of cancer patients.”

Since Pfizer introduced XALKORI (crizotinib) as the first TKI for the treatment of ALK-positive metastatic NSCLC in 2011, the availability of these medicines has created an opportunity to provide

patients with treatment options other than chemotherapy. However, lung cancer remains the leading cause of cancer-related death around the world.

While many ALK-positive metastatic NSCLC patients respond to initial TKI therapy, they typically experience tumor progression.[1,2]
Additionally, options for patients who progress after treatment with second-generation ALK TKIs, alectinib, brigatinib and ceritinib, are limited.[3] The approval of LORBRENA represents a new option for patients who have progressed on a second-generation ALK TKI, providing an opportunity to remain on oral therapy.

“The last decade has witnessed dramatic improvements in the treatment of metastatic ALK-positive non-small cell lung cancer due to earlier generation ALK biomarker-driven therapies. Yet almost all patients still relapse due to drug resistance, with a large proportion of patients developing new or worsening brain metastases,” said Alice T. Shaw, MD,PhD, Professor of Medicine at Harvard Medical School, and Director of the Center for Thoracic Cancers at Massachusetts General Hospital.