Generic Name:
Lorlatinib
Trade Name:
Lorbrena
Company:
Pfizer
Notes:

Pfizer announced FDA approval of a new indication for lorlatinib, 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.

Accelerated approval was 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.

While many ALK-positive metastatic NSCLC patients respond to initial TKI therapy, they typically experience tumor progression, stated Pfizer in a news release. In addition, options for patients who progress after treatment with second-generation ALK TKIs, alectinib, brigatinib and ceritinib, are limited. Approval of this indication represents a new option for patients who have progressed on a second-generation ALK TKI, providing an opportunity to remain on oral therapy.

In clinical trials, the most common (?20%) adverse reactions were edema, peripheral neuropathy, cognitive effects, dyspnea, fatigue, weight gain, arthralgia, mood effects, and diarrhea.
increased alkaline phosphatase.

The most frequent serious adverse reactions reported were pneumonia, dyspnea, pyrexia, mental status changes, and respiratory failure.

Fatal adverse reactions occurred in 2.7% percent of patients and included pneumonia, myocardial infarction, acute pulmonary edema, embolism, peripheral artery occlusion, and respiratory distress.

Medication Monitor Categories:
Supplemental Approvals