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

On November 2, 2018, FDA approved 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.

This indication was approved under accelerated approval on the basis of tumor response rate and duration of response. It was the third FDA approval Pfizer received for an oncology treatment, including two lung cancer medications, within 2 months.

Approval was based on a nonrandomized, dose-ranging and activity-estimating, multicohort, multicenter study evaluating lorlatinib for treatment of patients with ALK-positive metastatic NSCLC, who were previously treated with one or more ALK TKIs. A total of 215 patients with ALK-positive metastatic NSCLC were enrolled across various subgroups on the basis of prior treatment.

Among these patients, overall response rate was 48%, and 57% had previous treatment with more than one ALK TKI. In the trial, 69% of patients had a history of brain metastases, and intracranial response rate was 60%.

Among participants who received 100 mg once daily in the study, the most common adverse reactions were edema, peripheral neuropathy, cognitive effects, dyspnea, fatigue, weight gain, arthralgia, mood effects, and diarrhea.

The most frequent serious adverse reactions were pneumonia, dyspnea, pyrexia, mental status changes, and respiratory failure.
Medication Monitor Categories:
New Drug Approvals