FDA Approves Alunbrig for ALK-Positive Metastatic Non-Small-Cell Lung Cancer

Study showed 74% overall response rate for people who used brigatinib as their first ALK inhibitor.

May 25, 2020 By Food and Drug Administration (FDA)

On May 22, 2020, the Food and Drug Administration approved brigatinib (ALUNBRIG, ARIAD Pharmaceuticals Inc.) for adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

Today, the FDA also approved the Vysis ALK Break Apart FISH Probe Kit (Abbott Molecular, Inc.) as a companion diagnostic for brigatinib.

Efficacy was investigated in ALTA 1L (NCT02737501), a randomized (1:1), open-label, multicenter trial in adult patients with advanced ALK-positive NSCLC who had not previously received an ALK-targeted therapy. The trial required patients to have an ALK rearrangement based on a local standard of care testing.

The trial randomized 275 patients to receive brigatinib 180 mg orally once daily with a 7-day lead-in at 90 mg once daily (n=137) or crizotinib 250 mg orally twice daily (n=138). A subset of the clinical samples was retrospectively tested with the Vysis ALK Break Apart FISH Probe Kit. Of the enrolled patients, 239 had positive results using the Vysis diagnostic test (central results were negative for 20 patients and unavailable for 16 patients).

The major efficacy outcome measure was progression-free survival (PFS) evaluated by a blinded independent review committee according to RECIST 1.1. Additional efficacy outcome measures as evaluated by the BIRC was confirmed overall response rate (ORR).

Estimated median PFS for patients treated with brigatinib was 24 months (95% CI: 18.5, NE) compared with 11 months (95% CI: 9.2, 12.9) for those treated with crizotinib (HR 0.49; 95% CI: 0.35, 0.68; p<.0001). Confirmed ORR was 74% (95% CI: 66, 81) and 62% (95% CI: 53, 70), respectively.

The most common adverse reactions (≥25%) with brigatinib were diarrhea, fatigue, nausea, rash, cough, myalgia, headache, hypertension, vomiting, and dyspnea.

The recommended brigatinib dose is 90 mg orally once daily for the first 7 days; then increase to

180 mg orally once daily. Brigatinib may be taken with or without food.

View full prescribing information for ALUNBRIG.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted priority review. Brigatinib also received orphan drug designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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