FDA Approves Augtyro for ROS1-Positive Non-Small-Cell Lung Cancer

Repotrectinib led to tumor shrinkage in 79% of patients who had not previously used a tyrosine kinase inhibitor.

November 21, 2023 By Food and Drug Administration (FDA)

On November 15, 2023, the Food and Drug Administration approved repotrectinib (Augtyro, Bristol-Myers Squibb Company) for locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).

This is the first FDA approval that includes patients with ROS1-positive NSCLC who have previously received a ROS1 tyrosine kinase inhibitor (TKI), in addition to patients who are TKI naïve.

Click here for full prescribing information for Augtyro.

Approval was based on TRIDENT-1, a global, multicenter, single-arm, open-label, multi-cohort clinical trial (NCT03093116) which included patients with ROS1-positive locally advanced or metastatic NSCLC. Efficacy was evaluated in 71 ROS1 TKI-naïve patients who received up to 1 prior line of platinum-based chemotherapy and/or immunotherapy and 56 patients who received 1 prior ROS1 TKI with no prior platinum-based chemotherapy or immunotherapy.

The major efficacy outcome measures were overall response rate (ORR) and duration of response (DOR) according to RECIST v1.1 as assessed by blinded independent central review. Confirmed ORR in the ROS1 TKI naïve group was 79% (95% CI: 68, 88) and 38% (95% CI: 25, 52) in those patients receiving prior treatment with a ROS1 inhibitor. Median DOR was 34.1 months (95% CI: 25.6, not evaluable) and 14.8 months (95% CI: 7.6, not evaluable) in the two respective groups. Responses were observed in intracranial lesions in patients with measurable CNS metastases, and in patients with resistance mutations following TKI therapy.

The most common (>20%) adverse reactions were dizziness, dysgeusia, peripheral neuropathy, constipation, dyspnea, ataxia, fatigue, cognitive disorders, and muscular weakness.

The recommended repotrectinib dose is 160 mg orally once daily with or without food for 14 days, then increased to 160 mg twice daily, until disease progression or unacceptable toxicity.

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

This application was granted priority review, breakthrough designation, and fast track designation. FDA expedited programs are described 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.

This announcement was published by the Food and Drug Administration on November 16, 2023.
