FDA Approves Cyramza Plus Tarceva for First-Line Lung Cancer Treatment

Ramucirumab slowed disease progression more than a placebo when added to erlotinib.

June 1, 2020 By Food and Drug Administration (FDA)

On May 29, 2020, the Food and Drug Administration approved ramucirumab (CYRAMZA, Eli Lilly and Company) in combination with erlotinib for first-line treatment of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations.

Efficacy was evaluated in RELAY (NCT02411448), a multinational, randomized, double-blind, placebo-controlled, multicenter study in patients with previously untreated metastatic NSCLC whose tumors have EGFR exon 19 deletion or exon 21 (L858R) substitution mutations. A total of 449 patients were randomized (1:1) to receive either ramucirumab 10 mg/kg or placebo every 2 weeks as an intravenous infusion, in combination with erlotinib 150 mg orally once daily, until disease progression or unacceptable toxicity.

The major efficacy outcome measure was progression-free survival (PFS) as assessed by the investigator (RECIST 1.1). Additional efficacy outcome measures included overall survival (OS), overall response rate (ORR), and duration of response (DoR). Median PFS was 19.4 months in the ramucirumab plus erlotinib arm compared with 12.4 months in the placebo plus erlotinib arm (HR 0.59; 95% CI: 0.46, 0.76; $p<0.0001$).

ORR was 76% in the ramucirumab plus erlotinib arm and 75% in the placebo plus erlotinib arm, with median DoR of 18.0 months and 11.1 months, respectively. At the time of the final analysis of PFS, OS data were not mature as only 26% of the deaths required for the final analysis had occurred (HR 0.83; 95% CI: 0.53, 1.30).

The most common adverse reactions observed in patients treated with ramucirumab with erlotinib at a rate of ≥20% and ≥2% higher than placebo with erlotinib were infections, hypertension, stomatitis, proteinuria, alopecia, epistaxis, and peripheral edema. The most common laboratory abnormalities at a rate of ≥20% and ≥2% higher difference in incidence between arms were increased alanine aminotransferase, increased aspartate aminotransferase, anemia, thrombocytopenia, neutropenia, increased alkaline phosphatase, and hypokalemia.

The recommended dose of ramucirumab for metastatic NSCLC in combination with erlotinib is 10 mg/kg every 2 weeks.

View full prescribing information for CYRAMZA.

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

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 originally published on the Food and Drug Administration website on May 29, 2020.
