FDA Approves Vizimpro for Metastatic Non-Small-Cell Lung Cancer

Targeted therapy approved first-line treatment of cancer with specific genetic mutations.

September 27, 2018 By Food and Drug Administration (FDA)

On Sept. 27, 2018, the Food and Drug Administration approved tablets (VIZIMPRO, Pfizer Pharmaceutical Company) for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

Approval was based on a randomized, multicenter, open-label, active controlled trial (ARCHER 1050; NCT01774721) comparing the safety and efficacy of dacomitinib to gefitinib in 452 patients with unresectable, metastatic NSCLC. Patients were required to have no prior therapy for metastatic disease or recurrent disease with a minimum of 12 months disease-free after completion of systemic non-EGFR TKI-containing therapy; an Eastern Cooperative Oncology Group performance status of 0 or 1; and EGFR exon 19 deletion or exon 21 L858R substitution mutations. Patients were randomized (1:1) to receive either dacomitinib 45 mg orally once daily or gefitinib 250 mg orally once daily until disease progression or unacceptable toxicity.

The trial demonstrated a significant improvement in progression-free survival; no improvement in overall response rate or overall survival were demonstrated. The median progression-free survival, as determined by an independent review committee. was 14.7 and 9.2 months in the dacomitinib and gefitinib arms, respectively (hazard ratio 0.59; 95% CI: 0.47, 0.74; $p<0.0001$).

The prescribing information contains warnings and precautions for interstitial lung disease (ILD), diarrhea, and dermatologic adverse reactions. Of 394 patients who received dacomitinib, serious adverse reactions occurred in 27%. The most common adverse reactions resulting in discontinuation in of dacomitinib were diarrhea and ILD. The most common (>20%) adverse reactions of dacomitinib were diarrhea, rash, paronychia, stomatitis, decreased appetite, dry skin, decreased weight, alopecia, cough, and pruritus).

The recommended dacomitinib dose is 45 mg orally once daily with or without food.

View full prescribing information for VIZIMPRO.

FDA granted this application priority review and orphan drug 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.

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