FDA Approves Dacomitinib for Metastatic Non–Small Cell Lung Cancer

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On September 27, 2018, the U.S. Food and Drug Administration (FDA) approved dacomitinib tablets (Vizimpro) 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. The FDA also approved a premarket approval supplement expanding the labeling claim of the *therascreen EGFR RGQ PCR Kit* to allow its use as a companion diagnostic with dacomitinib for the first-line treatment of patients with NSCLC with *EGFR* exon 19 deletions or an exon 21 L858R mutation.

ARCHER 1050

Approval was based on the randomized, multicenter, open-label, active controlled ARCHER 1050 trial comparing the safety and efficacy of dacomitinib to gefitinib in 452 patients with unresectable, metastatic NSCLC. Patients were required to have had no prior therapy for metastatic or recurrent disease, with a minimum of 12 months disease-free after completion of systemic non-EGFR tyrosine kinase inhibitor–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 at 45 mg orally once daily or gefitinib at 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 was demonstrated. As determined by an independent review committee, the median progression-free survival was 14.7 and 9.2 months in the dacomitinib and gefitinib arms, respectively (hazard ratio = 0.59; 95% confidence interval: 0.47—0.74; $P < .0001$).

The prescribing information contains warnings and precautions for interstitial lung disease, 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 of dacomitinib were diarrhea and interstitial lung disease. The most common (> 20%) adverse reactions to 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.