

New Drug Approvals

Generic Name (Trade Name—Company)

October 1, 2018

Dacomitinib

(Vizimpro—Pfizer)

New kinase inhibitor approved for treatment of EGFR-mutated metastatic non–small cell lung cancer

Uses/Notes

[FDA has approved](#) dacomitinib, a kinase inhibitor for 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.

Safety and efficacy of dacomitinib were demonstrated in ARCHER 1050, a randomized, multicenter, multinational, open-label study in which 452 patients were randomized 1:1 to treatment with dacomitinib or with gefitinib. A statistically significant improvement was demonstrated in patients receiving dacomitinib compared with gefitinib.

The most common adverse reactions were diarrhea, rash, paronychia, stomatitis, decreased appetite, dry skin, decreased weight, alopecia, cough, and pruritus.

The most common serious adverse reactions reported were diarrhea and interstitial lung disease. The full prescribing information can be found [here](#).

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<http://www.aphanet.org/new-drug-approvals/new-kinase-inhibitor-approved-treatment-egfr-mutated-metastatic-non-small-cell>

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