# FDA Approves Dabrafenib, Trametinib Combo to Treat BRAF V600E NSCLC

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The U.S. Food and Drug Administration (FDA) announced approval of Tafinlar (dabrafenib) and Mekinist (trametinib) to be delivered in combination for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutations.

The therapies, developed by Novartis Pharmaceuticals, are the first to be approved specifically for the treatment of patients with BRAF V600E mutation-positive metastatic NSCLC.

The FDA also approved the OncomineDx Target Test, by Thermo Fisher Scientific, a next generation sequencing (NGS) test designed to detect multiple genetic mutations associated with lung cancer, including EGFR, BRAF, and ROS1 gene mutations. The test allows for the detection of multiple gene mutations from a single tissue specimen and can be used to

select patients with the BRAF V600E mutation for treatment with Tafinlar and Mekinist combination therapy.

The approvals were based on the Phase 2 BRF113928 study (NCT01336634), an international, multicenter, non-randomized, open-label clinical trial in which 93 patients with confirmed BRAF V600E mutation-positive metastatic NSCLC were treated with Tafinlar and Mekinist, and 78 received single-agent Tafinlar.

Of the 93 patients, 36 had received no prior systemic therapy, while 57 had received at least one platinum-based chemotherapy regimen followed by disease progression.

The overall response rate for the combination of the two therapies based on radiological data was 63%, with a median duration of response of 12.6 months in patients who had not received prior systemic therapy. Among patients who previously had received chemotherapy, 61% responded to treatment. While the median duration of response has not been reached yet, 59% of responders had response durations greater than six months.

Adverse reactions attributed to therapy were similar to those reported in prior approvals for patients with melanoma and included elevated temperature, fatigue, nausea, diarrhea, vomiting, decreased appetite, dry skin, rash, and edema. More serious adverse reactions included low levels of white and red blood cells, high blood sugar and phosphate levels, and elevation in liver enzymes. Tafinlar and Mekinist were discontinued due to adverse effects in 18% and 19% of patients, respectively.

The medications are dosed orally with Tafinlar given twice daily and Mekinist given once daily.