Supplemental Approvals

Generic Name (Trade Nameâ€"Company)

Uses/Notes

July 9, 2018

Encorafenib, binimetinib

(Braftovi, Mektovi—Array BioPharma)

Agents approved in combination for unresectable or metastatic melanoma with BRAF mutations

FDA approved encorafenib and binimetinib in combination for patients with unresectable or metastatic melanoma with a *BRAF V600E* or *V600K* mutation, as detected by an FDA-approved test.

Approval was based on a randomized, active-controlled, open-label, multicenter trial in 577 patients with *BRAF V600E* or *V600K* mutation-positive unresectable or metastatic melanoma. Patients were randomized (1:1:1) to receive binimetinib 45 mg twice daily plus encorafenib 450 mg once daily, encorafenib 300 mg once daily, or vemurafenib 960 mg twice daily. Treatment continued until disease progression or unacceptable toxicity.

The major efficacy measure was progression-free survival (PFS) using RECIST 1.1 response criteria and assessed by blinded independent central review. The median PFS was 14.9 months for patients receiving binimetinib plus encorafenib and 7.3 months for the vemurafenib monotherapy arm (hazard ratio 0.54 [95% CI 0.41–0.71], *P*

The most common (?25%) adverse reactions in patients receiving the combination were fatigue, nausea, diarrhea, vomiting, abdominal pain, and arthralgia. Discontinuation of therapy due to adverse reactions occurred in 5% of patients receiving the combination; the most common reasons were hemorrhage and headache.

FDA also granted approval of the THxID BRAF Kit (bioMérieux) as a companion diagnostic for these therapeutics.

The recommended doses are binimetinib 45 mg orally twice daily and encorafenib 450 mg orally once daily.

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