FDA approves Braftovi + Mektovi

August 2018—Array BioPharma announced that the FDA has approved Braftovi (encorafenib) capsules in combination with Mektovi (binimetinib) tablets for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or BRAF V600K mutation, as detected by an FDA-approved test. Approval was based on the randomized, active-controlled, open-label, multicenter COLUMBUS trial in which 577 patients with BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma 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 FDA also granted approval of the THxID BRAF Kit (BioMérieux) as a companion diagnostic for these therapeutics.

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