RXADVANCE
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Braftovi (encorafenib) Capsules
Clinical Update

Clinical Update: FDA Approves Braftovi (encorafenib) in Combination with Cetuximab for the Treatment of BRAFV600E-Mutant Metastatic Colorectal Cancer (CRC) After Prior Therapy.
FDA approval date: April 8, 2020.

Braftovi (encorafenib) is a kinase inhibitor indicated:

- in combination with binimetinib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.
- in combination with cetuximab, for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.

U.S. Food and Drug Administration (FDA) has approved Braftovi® (encorafenib) in combination with cetuximab (marketed as ERBITUX®) for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAFV600E mutation, as detected by an FDA-approved test, after prior therapy. The approval is based on results from the BEACON CRC trial, the only Phase 3 trial to specifically study patients with previously treated metastatic CRC with a BRAFV600E mutation.

BEACON CRC: Braftovi in combination with cetuximab was evaluated in the randomized, active-controlled, open-label, multicenter, Phase 3 BEACON CRC trial. Eligible patients were required to have BRAFV600E mutant metastatic CRC, as detected by an FDA-approved test, with disease progression after one or two prior regimens.

Patients were randomized 1:1:1 to one of the following treatment arms:

- Braftovi 300 mg orally once daily in combination with cetuximab (Braftovi/cetuximab arm)
- Braftovi 300 mg orally once daily in combination with cetuximab and binimetinib
- Irinotecan with cetuximab or FOLFIRI with cetuximab (control arm)

The major efficacy outcome measure was OS. Additional efficacy outcome measures included PFS, ORR, and duration of response (DoR) as assessed by blinded independent central review (BICR). OS and PFS were assessed in all randomized patients. ORR and DoR were assessed in the subset of the first 220 patients included in the randomized portion of the Braftovi/cetuximab and control arm of the study. A total of 220 patients were randomized to the Braftovi/cetuximab arm and 221 to the control arm.

The trial was conducted at over 200 investigational sites in North America, South America, Europe and the Asia Pacific region. The BEACON CRC trial was conducted with support from Ono Pharmaceutical Co. Ltd., Pierre Fabre and Merck KGaA, Darmstadt, Germany (support is for sites outside of North America).