FDA Approves Braftovi Combination for Metastatic Colon Cancer

Encorafenib plus cetuximab improved survival in a Phase III study.

April 13, 2020 By Food and Drug Administration (FDA)

FDA approves encorafenib in combination with cetuximab for metastatic colorectal cancer with a BRAF V600E mutation

On April 8, 2020, the Food and Drug Administration approved encorafenib (Braftovi, Array BioPharma Inc.) in combination with cetuximab for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, detected by an FDA-approved test, after prior therapy.

Efficacy was evaluated in a randomized, active-controlled, open-label, multicenter trial (BEACON CRC; NCT02928224). Eligible patients were required to have BRAF V600E mutation-positive metastatic CRC (detected by the Qiagen therascreen BRAF V600E RGQ PCR kit) with disease progression after one or two prior regimens.

A total of 220 patients were randomized to encorafenib (300 mg orally once daily) in combination with cetuximab and 221 patients were randomized to the control arm of either irinotecan or FOLFIRI with cetuximab.

The major efficacy outcome measure was overall survival (OS). Additional efficacy outcome measures included progression-free survival (PFS), overall confirmed response rate (ORR), and duration of response (DoR). ORR and DoR were assessed by blinded independent central review in the subset of the first 220 patients randomized to receive either encorafenib plus cetuximab or the control arm.

Median OS was 8.4 months (95% CI: 7.5, 11.0) in the encorafenib and cetuximab arm compared to 5.4 months (95% CI: 4.8, 6.6) in the control arm (HR 0.60; 95% CI: 0.45, 0.79; p=0.0003). Median PFS was 4.2 months (95% CI: 3.7, 5.4) in the encorafenib and cetuximab arm compared to 1.5 months (95% CI: 1.4, 1.7) in the control arm (HR 0.40; 95% CI: 0.31, 0.52; p<0.0001). ORR was 20% (95% CI: 13%, 29%) and 2% (95% CI: 0%, 7%), respectively. Median DOR was 6.1 months (95% CI: 4.1, 8.3) for the encorafenib and cetuximab arm and not reached (95% CI: 2.6, NR) in the control arm.

The most common adverse reactions (≥25%) for encorafenib with cetuximab were fatigue,

nausea, diarrhea, dermatitis acneiform, abdominal pain, decreased appetite, arthralgia, and rash.

The recommended encorafenib dose is 300 mg orally once daily in combination with cetuximab.

View full prescribing information for Braftovi.

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

This application was granted priority review and breakthrough therapy designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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