FDA Grants Accelerated Approval to Bosulif for Newly Diagnosed Chronic Melogenous Leukemia

New option for patients with newly diagnosed chronic phase Philadelphia chromosome positive chronic myelogenous leukemia.

December 19, 2017 By Food and Drug Administration (FDA)

On December 19, 2017, the Food and Drug Administration granted accelerated approval to bosutinib (BOSULIF, Pfizer Inc.) for treatment of patients with newly-diagnosed chronic phase (CP) Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML).

Approval was based on data from an open-label, randomized, multicenter trial (BFORE, NCT02130557) in 487 patients with Ph+ newly-diagnosed CP CML who were randomized to receive either bosutinib 400 mg once daily or imatinib 400 mg once daily. The major efficacy outcome measure was major molecular response (MMR) at 12 months, defined as ≤0.1% BCR ABL ratio on international scale (corresponding to ≥3 log reduction from standardized baseline) with a minimum of 3000 ABL transcripts as assessed by the central laboratory. MMR at 12 months was 47.2% (95% CI: 40.9, 53.4) in the bosutinib arm and 36.9% (95% CI: 30.8, 43.0) in the imatinib arm (p=0.0200).

Most common adverse reactions in patients with newly-diagnosed CML (incidence ≥20%) are diarrhea, nausea, thrombocytopenia, rash, increased alanine aminotransferase, abdominal pain, and increased aspartate aminotransferase.

FDA first approved bosutinib in 2012 for treatment of patients with chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.

The recommended dose of bosutinib for newly-diagnosed chronic phase Ph+ CML is 400 mg orally once daily with food.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/203341s009lbl.pdf.

FDA granted priority review and Orphan Drug designation to bosutinib for this application. As a condition of accelerated approval, further follow-up of patients in the BFORE trial is required. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for

Serious Conditions-Drugs and Biologics, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.

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 by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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