

## Bosulif<sup>®</sup> (bosutinib) – Expanded indication, new formulation approval

- On September 26, 2023, the [FDA approved](#) Pfizer's [Bosulif \(bosutinib\)](#), for treatment of adult and pediatric patients 1 year of age and older with chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), newly-diagnosed or resistant or intolerant to prior therapy.
  - Bosulif was previously approved for this indication in adults only.
- Bosulif is also approved for the treatment of adult patients with accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy.
- In addition to the expanded indication, the [FDA approved](#) a new capsule formulation of Bosulif. Bosulif was previously available as a tablet.
- The approval of Bosulif for the expanded indication was based on BCHILD, a non-randomized, open-label study in 28 pediatric patients with CP Ph+ CML. The study included 28 patients with resistance or intolerance to prior therapy and 21 patients with newly diagnosed Ph+ CML. Efficacy was assessed based on complete cytogenetic response (CCyR), major cytogenetic response (MCyR) and major molecular response (MMR).
  - The MCyR and CCyR among patients with newly diagnosed CP Ph+ CML were 76.2% (95% CI: 52.8, 91.8) and 71.4% (95% CI: 47.8, 88.7), respectively. The MMR was 28.6% (95% CI: 11.3, 52.3).
  - The MCyR and CCyR among patients with resistant or intolerant CP Ph+ CML were 82.1% (95% CI: 63.1, 93.9) and 78.6% (95% CI: 59.0, 91.7), respectively. The MMR was 50.0% (95% CI: 30.6, 69.4).
- The recommended dose of Bosulif for pediatric patients with newly-diagnosed CP Ph+ CML is 300 mg/m<sup>2</sup> orally once daily and the recommended dosage for pediatric patients with CP Ph+ CML that is resistant or intolerant to prior therapy is 400 mg/m<sup>2</sup> orally once daily (refer to the drug label for complete dose recommendations).
  - For patients who are unable to swallow capsules, the contents of the capsules can be mixed with applesauce or yogurt.
  - Refer to the Bosulif drug label for dosing for adults.
- Pfizer's launch plans for Bosulif capsules are pending. Bosulif capsules will be available in a 50 mg and 100 mg strength.