Bosulif® (bosutinib) – Expanded indication

- On December 19, 2017, Pfizer announced the FDA approval of Bosulif (bosutinib) for the treatment of adult patients with newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML).
    - This indication is approved under accelerated approval based on molecular and cytogenetic response rates. Continued approval for this indication may be contingent upon verification and confirmation of clinical benefit in an ongoing long-term follow up trial.
    - Previously, Bosulif was only approved for CP, accelerated phase (AP), or blast phase (BP) Ph+ CML with resistance or intolerance to prior therapy.
- CML is a rare blood cancer that accounts for 10-15% of all incident leukemia cases. In the U.S., approximately 48,000 people are living with CML. Around 9,000 new CML cases were diagnosed in the U.S. in 2017.
- Efficacy to support the expanded indication was based on data from a clinical study of 536 patients randomized to Bosulif or Gleevec® (imatinib). The primary efficacy endpoint was major molecular response (MMR) at 12 months.
    - Bosulif was associated with a significantly higher rate of patients achieving MMR (47.2%) vs. the rate achieved in patients treated with Gleevec (36.9%), a current standard of care ($p = 0.02$).
    - Complete cytogenic response rate by 12 months was 77.2% (95% CI: 72.0, 82.5) for patients treated with Bosulif vs. 66.4% for patients treated with Gleevec ($p = 0.0075$).
- The recommended dose of Bosulif for the treatment of newly diagnosed CP Ph+ CML is 400 mg orally once daily with food.
    - The recommended dose of Bosulif for the treatment of CP, AP or BP Ph+ CML with resistance or intolerance to prior therapy is 500 mg orally once daily with food.