

FDA approves Bosulif for pediatric patients with CML

October 2023—The FDA approved bosutinib (Bosulif, Pfizer) for pediatric patients who are one year old and older with chronic phase Ph+ chronic myelogenous leukemia that is newly diagnosed or resistant or intolerant to prior therapy. Efficacy was evaluated in the BCHILD trial (NCT04258943), a multicenter, nonrandomized, open-label trial conducted to identify a recommended bosutinib dose in pediatric patients with newly diagnosed chronic phase Ph+ CML and resistant or intolerant Ph+ CML; estimate the safety, tolerability, and efficacy; and evaluate bosutinib pharmacokinetics in this patient population.

This application was granted priority review and orphan drug designation.

[Pfizer](#), 800-438-1985