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Bristol-Myers Squibb receives positive CHMP Opinion recommending Sprycel for Pediatric Patients

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The application is based on data from CA180-372 (NCT01460160), an ongoing Phase 2 trial evaluating the addition of Sprycel to a chemotherapy regimen modeled on a Berlin-Frankfurt-Munster high-risk backbone in pediatric patients with newly diagnosed Ph+ ALL.



Bristol-Myers Squibb Company has announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has recommended the expanded approval of Sprycel (dasatinib), in combination with chemotherapy, to include the treatment of pediatric patients with newly diagnosed Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL). The positive opinion includes the tablet form of Sprycel and the powder for oral suspension formulation, which was first approved by the European Commission (EC) in July 2018, making Sprycel the only tyrosine kinase inhibitor with a formulation developed for administration in pediatric patients and patients who cannot swallow tablets. The CHMP recommendation will now be reviewed by the EC, which has the authority to approve medicines for the European Union (EU).

“We are pleased with today’s CHMP recommendation for Sprycel in pediatric patients with Ph+ ALL, and look forward to the possibility of expanding Sprycel’s pediatric indications in the EU to include young patients with this particularly high-risk leukemia,” said Fouad Namouni, M.D., head, oncology development, Bristol-Myers Squibb.

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