FDA Approves Dasatinib for Pediatric Patients with CML

FDA approves dasatinib (Sprycel) for children with Philadelphia chromosome-positive chronic myeloid leukemia.

November 9, 2017 By Food and Drug Administration (FDA)

On November 9, 2017, the Food and Drug Administration granted regular approval to dasatinib (SPRYCEL, Bristol-Myers Squibb Co.) for the treatment of pediatric patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in the chronic phase.

Approval was based on data from 97 pediatric patients with chronic phase CML evaluated in two trials—a phase 1, open-label, non-randomized, dose-ranging trial and a phase 2, open-label, non-randomized trial. Fifty-one patients exclusively from the phase 2 trial were newly diagnosed with chronic phase CML and 46 patients (17 from the phase 1 trial and 29 from the phase 2 trial) were resistant or intolerant to previous treatment with imatinib. The majority of patients were treated with dasatinib tablets 60 mg/m2 once daily. Patients were treated until disease progression or unacceptable toxicity.

After 24 months of treatment, 96.1% of newly diagnosed patients (95% CI: 86.5, 99.5) and 82.6% of patients resistant or intolerant to imatinib (95% CI: 68.6, 92.2) had complete cytogenic response (CCyR). With a median follow-up of 4.5 years in newly diagnosed patients and 5.2 years in imatinib-resistant or -intolerant patients, the median durations of CCyR, major cytogenic response (MCyR), and major molecular response (MMR) could not be estimated as more than half of the responding patients had not progressed at the time of data cut-off.

Adverse reactions reported in ~10% of dasatinib-treated pediatric patients (n=97) were headache, nausea, diarrhea, skin rash, vomiting, pain in extremity, abdominal pain, fatigue, and arthralgia.

The recommended dose of dasatinib in pediatric patients is based on body weight.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021986s020lbl.pdf.

FDA granted priority review and orphan product designation to dasatinib for this indication. 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/ucm

358301.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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