FDA approves Imbruvica for pediatric chronic graft versus host disease

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The U.S. Food and Drug Administration has approved Imbruvica

(ibrutinib) for pediatric patients with chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy.

The approval was based on a trial of 47 patients (age range, 1 to 19 years; 70 percent male) with moderate or severe cGVHD. At week 25, the overall response rate was 60 percent, with a median duration of response of 5.3 months. From first response to death or new systemic therapies for cGVHD, the median time was 14.8 months. Anemia, musculoskeletal pain, pyrexia, diarrhea, pneumonia, abdominal pain, stomatitis, thrombocytopenia, and headache were the most common adverse reactions reported (≥20 percent).

The FDA recommends an oral dosage of 420 mg of Imbruvica once a day for patients aged 12 years and older with cGVHD and 240 mg/m^2 orally once daily (up to a dose of 420 mg) for patients aged 1 year to younger than 12 years with cGVHD, until cGVHD progression, recurrence of an underlying malignancy, or unacceptable toxicity. Formulations include capsules, tablets, and an oral suspension.

Applications for this approval were granted priority review, and Imbruvica was granted orphan drug designation. Approval of Imbruvica was granted to Pharmacyclics.

More information: FDA Approval