Rituxan approved for pediatric patients with rare vasculitis diseases

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(HealthDay)—Rituxan (rituximab) injection was granted the first

approval for a drug to treat granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) in combination with glucocorticoids in children 2 years and older, the U.S. Food and Drug Administration announced Friday.

The agency noted that pediatric patients with GPA, previously known as Wegener's granulomatosis, and MPA have a safety profile that is consistent with that of the known safety profile of Rituxan in adults with autoimmune diseases, including GPA and MPA.

In an international multicenter, open-label, single-arm, uncontrolled study, 25 patients ages 6 to 17 years with active GPA and MPA were treated with Rituxan or non-U.S.-licensed rituximab. Before starting treatment, all patients received methylprednisolone. After a six-month remission induction phase, patients who had not achieved remission could receive additional treatment at the investigator's discretion. At the six-month mark, 14 patients were in remission, and at 18 months, all 25 patients had achieved remission. In addition to these data, pharmacokinetic and safety information supported the approval of Rituxan for 2- to 5-year-old patients with GPA/MPA.

The most commonly reported side effects in pediatric patients included infections, infusion-related reactions, and nausea. Pediatric GPA and MPA patients treated with the study products have also experienced hypogammaglobulinemia. Other common side effects of Rituxan are lymphopenia and anemia. Physicians should also monitor patients for tumor lysis syndrome, cardiac adverse reactions, renal toxicity, and bowel obstruction and perforation.

A Boxed Warning on the prescription information for Rituxan advises of increased risks for fatal infusion reactions, potentially fatal severe skin and mouth reactions, hepatitis B virus reactivation that could cause serious liver problems, and progressive multifocal leukoencephalopathy.

Approval was granted to Genentech. Rituxan was approved for use in adult patients with GPA and MPA in 2011.

More information: More Information