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FDA approves Promacta to treat pediatric patients with chronic immune thrombocytopenic purpura

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The U.S. Food and Drug Administration today approved Promacta (eltrombopag) to treat low blood platelet count in pediatric patients – ages one year and older – with a rare blood disorder called chronic immune thrombocytopenic purpura (ITP). Promacta can be used in these children when they have not achieved an appropriate response using other ITP medicines or surgery to remove the spleen.

ITP is a disorder that results in an abnormally low number of platelets, the cells that help your blood clot. Without enough platelets, bleeding can occur under the skin, in mucous membranes (such as in the mouth) or in other parts of the body.

"Today's approval of Promacta emphasizes the FDA's commitment to fully developing treatments in areas of pediatric hematology and oncology," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "This new use in ages one and up builds on a recent approval for ages six years and up, and fills an unmet need for young children whose disease has progressed after use of other available treatments."

Promacta helps increase blood platelet production and is available as a tablet taken once-daily or as a powder that is mixed with liquid for children ages one to five to take orally. It was first approved in 2008 to treat adult patients with the same condition as the new pediatric indication.

Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.

The efficacy and safety of Promacta in pediatric patients ages one to 17 years with chronic ITP was evaluated in two double-blind, placebo-controlled trials of 159 participants where the primary endpoint was an increase in platelet counts. In the first trial (n=67), patients were randomly assigned to receive either Promacta or placebo daily for seven weeks. Of those taking Promacta, 62 percent had an improvement in platelet counts without rescue therapy between weeks one and six, compared to 32 percent in the placebo group. In the second trial (n=92), patients received either Promacta or placebo daily for 13 weeks and in those treated with Promacta, 41 percent experienced increased platelet counts for at least six out of eight weeks between weeks five to 12, compared to 3 percent of patients receiving placebo. In both trials, patients taking Promacta also had less need for other treatments to increase their platelet counts, such as corticosteroids or platelet transfusions. Among patients taking one or more ITP medications at the start of the trials, about half were able to reduce or discontinue their use of these medications, primarily corticosteroids.

The most common side effects of treatment with Promacta in children ages one and older were infections of the upper respiratory tract or nose and throat (symptoms including fever, cough, nasal congestion, runny nose and sore throat), diarrhea, abdominal pain, rash and increase in liver enzymes.

The safety and efficacy of Promacta in pediatric patients younger than one year with ITP, or in pediatric patients with thrombocytopenia associated with chronic hepatitis C and severe aplastic anemia, have not been established.

The FDA granted Promacta orphan drug designation because it treats a rare disease. Orphan drug designation provides financial incentives – like tax credits, user fee waivers, and eligibility for market exclusivity – to promote rare disease drug development.

Promacta is manufactured by Novartis in East Hanover, New Jersey.

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