

FDA APPROVES NEW DRUG TO TREAT ITP

Rockville, MD, November 21, 2008 - PROMACTA® (eltrombopag), the first oral thrombopoietin (TPO) receptor agonist, has been granted accelerated approval by the United States Food and Drug Administration (FDA) to treat adults with chronic immune (idiopathic) thrombocytopenic purpura (ITP). The drug is expected to be made available by next week.

"It is very important for chronic ITP patients to have new treatment options to manage the symptoms of this serious and, at times, life-threatening disease. In addition, many people with chronic ITP are concerned about everyday activities for fear of an accidental bump or unanticipated bruise that may lead to bleeding," said Craig Conway, executive director of the Platelet Disorder Support Association. "The approval of this new product represents a promising new treatment option that offers hope to the ITP community."

Developed by GlaxoSmithKline (GSK), in partnership with Ligand Pharmaceuticals Inc. (LGND), PROMACTA is designed to increase platelet counts and reduce or prevent bleeding and is approved for use in ITP patients who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

"Preventing platelet destruction has always been the primary means of treating patients with ITP. Recent advances, like the clinical trials of PROMACTA, show that increasing the production of platelets may also play a significant role in treating this disorder," said James Bussel, M.D., director of the Platelet Disorders Center, Children's Cancer and Blood Foundation Division of New York Presbyterian/Weill Cornell Medical Center. "The entire ITP community, including physicians, patients and their families, may benefit from this shift in thinking and these innovative new treatments."

The FDA approval of PROMACTA is based on data from two pivotal studies in the short-term treatment and one ongoing long-term treatment study of patients with chronic ITP. The drug will carry the FDA's strictest black-box warning, discussing various possible safety problems including liver damage, fibrous deposits in the bone marrow, and the possibility that once PROMACTA is stopped, platelet counts could drop below what they were before beginning treatment.

In accordance with the FDA's requirements to help assure the appropriate and safe use of PROMACTA, GSK is launching PROMACTA CARES, a single source of information, education and support for healthcare professionals and patients. Prescribers and pharmacies must enroll in PROMACTA CARES before they can prescribe or dispense PROMACTA. Similarly, patients are required to enroll in PROMACTA CARES before they can receive the drug. Additionally, PROMACTA CARES has an optional component: reimbursement support for the uninsured and under-insured.

More information about the PROMACTA CARES program can be found by calling 1-877-9-PROMACTA or by visiting www.PROMACTACARES.com. Program hours are 8:30 AM to 8:00 PM ET, Mondays through Fridays.

About ITP

ITP, immune (idiopathic) thrombocytopenic purpura, is an autoimmune disease. In autoimmune diseases, the body mounts an immune attack toward one or more seemingly normal organ systems. In ITP, platelets are the target. They are marked as foreign by the immune system and eliminated in the spleen and sometimes, the liver. In addition to increased platelet destruction, some people with ITP also have impaired platelet production. Without a sufficient number of platelets, a person with ITP is subject to spontaneous bleeding or bruising.

About PDSA

The Platelet Disorder Support Association is dedicated to enhancing the lives of people with immune thrombocytopenic purpura (ITP) and other platelet disorders through education, advocacy and research. For more information, please contact us at 1-87-PLATELET or visit our Web site at www.pdsa.org.

Contact: Caroline Kruse
(301) 770-6636
ckruse@pdsa.org