

FDA APPROVES NEW DRUG TO TREAT ITP

August 25, 2008

Nplate (romiplostim), the first product that directly stimulates the bone marrow to make more platelets in splenectomized (spleen removed) and non-splenectomized adults with chronic immune thrombocytopenic purpura (ITP), is today being distributed for use by physicians and patients following U.S. Food and Drug Administration approval last Friday. Amgen Inc's drug works by raising and sustaining platelet counts, representing a different approach than other approved ITP treatments.

"Until now, patients suffering from chronic ITP have had limited available treatment options, many of which are often unsuitable for long-term use due to side effects and tolerability issues," said David J. Kuter, M.D., Chief of Hematology, Massachusetts General Hospital, Boston. "Nplate represents the first long-term treatment for adult chronic ITP patients, providing a new treatment approach for this chronic disease."

The FDA approval of Nplate was based on efficacy and safety results from two main clinical studies of adult patients with chronic ITP, including both splenectomized and non-splenectomized patients. Combined data from both trials shows clinically relevant bleeding events were significantly reduced by half in patients treated with Nplate compared to placebo.

"For those suffering from ITP, the daily fear of experiencing a serious bleeding episode can be emotionally stressful and extremely difficult for both patients and their families. We welcome the addition of new treatment options which offer new hope for the treatment of this serious disease," said Craig Conway, executive director of the Platelet Disorder Support Association.

FDA regulators said they would require all patients who receive the drug to enroll in a long-term safety study because of some risks associated with it. Safety concerns with Nplate include fibrous deposits in the bone marrow and the possibility that once Nplate is stopped, platelet counts could drop below what they were before beginning treatment.

In response, Amgen also announced it will launch the Nplate™ NEXUS Program to provide treatment access and patient support. Through the Nplate™ NEXUS Program, eligible patients who are uninsured, underinsured, or unable to afford their insurance co-payments may be able to receive reimbursement support and other assistance from Amgen.

More information about the Nplate™ NEXUS Program is available by calling 1-877-NPLATE1 (1-877-675-2831), or by visiting www.nplate.com. Additional information from the FDA and Amgen can be found on the PDSA Web site [here](#).

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.

About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

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