Nplate® (romiplostim)
Fact Sheet

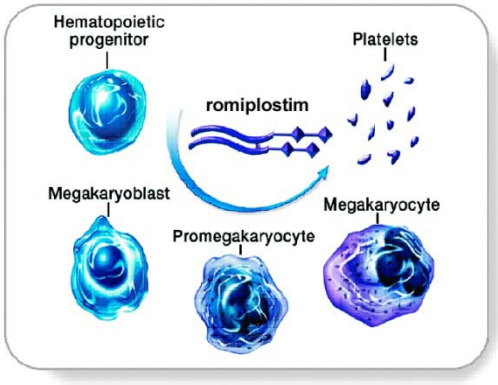
AMGEN CONTACT INFORMATION

U.S. Media: 805-447-1423
cassidy@amgen.com

Investor Relations: 805-447-1060
Investor.relations@amgen.com

What is Nplate® (romiplostim)?

Nplate (romiplostim) represents a novel treatment approach to the management of adult chronic immune (idiopathic) thrombocytopenic purpura (ITP), a chronic autoimmune disease.



Unlike most current treatments used to treat chronic ITP, which work to prevent platelet destruction, Nplate increases platelet production, representing a novel treatment approach for the treatment of ITP. Nplate has been shown to increase and sustain platelet counts for many patients with chronic ITP. Platelets, also called thrombocytes, are specialized blood cells needed to prevent bleeding.

In the U.S., Nplate is indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. Nplate should not be used in an attempt to normalize platelet counts.

Nplate is the first treatment specifically developed for chronic ITP. It is also being investigated for potential use in pediatric ITP, myelodysplastic syndromes (MDS), and chemotherapy-induced thrombocytopenia (CIT).

What is Immune Thrombocytopenic Purpura (ITP)?

In adults, ITP is a rare, serious and often chronic autoimmune disorder characterized by low platelet counts in the blood (a condition known as thrombocytopenia).

Platelets, also called thrombocytes, are specialized blood cells needed to prevent bleeding. Low platelet counts leave adult patients with ITP at risk for bleeding events. The risk of a serious bleeding event increases when platelet counts drop to less than 30,000 platelets per microliter of blood. In extreme cases, death can occur due to an intracerebral hemorrhage (bleeding into the brain).[1]

ITP occurs when immune system cells (specialized lymphocytes) produce antibodies that cause the destruction of platelets in the spleen and other organs. As such, ITP has historically been considered a disease of platelet destruction. However, recent data also suggest that low platelet counts in the blood may be caused by the inability of the body's natural processes to produce platelets. Therefore, increasing the rate of platelet production may help address low platelet counts associated with ITP.[2]

What is a Peptibody?

The peptibody is a novel platform developed by scientists at Amgen. A peptibody is an engineered protein, made by recombinant DNA technology, with attributes of both peptides and antibodies, but is distinct from each. The Nplate peptibody protein has been designed to bind to the TPO receptor thereby stimulating platelet production.

- The TPO-receptor binding domain stimulates the TPO receptor (also called the c-mpl receptor), which has been shown to increase platelet production.

- The Fc domain is a portion of human antibody (IgG) called the constant (or Fc) domain. This domain increases the half-life of the peptibody protein in the blood stream by binding to another receptor called neonatal Fc component (FcRn). Receptors for the Fc portion (FcR) of IgG antibody are widely expressed on cells of the immune system where they function to modulate cellular and humoral immunity.[3]

Regulatory Status

Nplate was the first platelet producer approved for chronic ITP by the regulatory bodies in Australia, the EU, Canada, Russia and the U.S., and is under review in Switzerland and Mexico. Nplate also has received orphan designation for chronic ITP in the U.S. (2003), the EU (2005), Switzerland (2005) and Japan (2006).

Important Product Safety Information

Serious adverse reactions associated with Nplate in clinical studies were bone marrow reticulin deposition and worsening thrombocytopenia after Nplate discontinuation. Additional risks include bone marrow fibrosis, thrombotic/thromboembolic complications, lack or loss of response to Nplate, hematological malignancies and progression of malignancy in patients with a pre-existing hematological malignancy or myelodysplastic syndrome (MDS).

Nplate is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than chronic ITP.

Complete Blood Counts (CBCs), including platelet counts and peripheral blood smears, should be monitored prior to initiation, throughout, and following discontinuation of Nplate therapy.

Nplate is available only through a restricted distribution program called Nplate(R) NEXUS (Network of Experts Understanding and Supporting Nplate and Patients) Program.

In the placebo-controlled studies, headache was the most commonly reported adverse drug reaction.

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[1] Platelet Disorder Support Association. About ITP Fact Sheet. http://www.pdsa.org/itp-information/index.html. Accessed November 24, 2009.
[2] Kuter, D., Bussel, J. et al. Efficacy of Romiplostim in Patients with Chronic Immune Thrombocytopenic Purpura: A Double-Blind Randomised Controlled Trial. *Lancet*. 2008: 371. 395-396.
[3] Davis, R. Haitaeo L. et al. Definition of an Fc Receptor-Related Gene (FcRX) Expressed in Human and Mouse B Cells. *International Immunology*. 2002; 14:1075-1083.