

Amgen Inc new study shows Nplate(R) significantly reduces splenectomy rate and treatment failure i

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Amgen Inc. released the results of a new study comparing Nplate(R) (romiplostim) to the medical standard of care (SOC) in non-splenectomised adult patients with chronic immune thrombocytopenic purpura (ITP). Chronic ITP is a serious autoimmune disorder characterised by low platelet counts in the blood (thrombocytopenia), which can lead to serious bleeding events. The study results show Nplate significantly reduced the incidences of splenectomy and treatment failures in non-splenectomised adult patients with chronic ITP when compared to medical SOC. The results were presented today as an oral presentation at the 14th congress of the European Hematology Association.

Dr. Mathias Rummel, head of hematology at the Hospital of the Justus-Liebig University, Giessen, Germany said, In this study, patients receiving Nplate experienced significant clinical efficacy benefits, including a reduction in bleeding events, compared to the standard of care. Nplate is a unique treatment option that can help us better manage patients with chronic ITP. It addresses an unmet medical need for our patients as it increases platelet production and avoids immune suppression. The study results show that only 8 percent of Nplate patients (13/157) underwent splenectomy or discontinued the study prior to reporting a splenectomy compared with 35 percent of patients (27/77) in the SOC group. Furthermore, 12 percent of Nplate patients (19/157) experienced treatment failure or discontinued the study compared with 27 percent of the SOC patients (21/77). Treatment failures were defined as patients having platelet counts less than or equal to 20,000 platelets per microliter for four consecutive weeks at the highest recommended dose and schedule, a major bleeding event, and/or a change in therapy due to intolerable side effects or bleeding symptoms. Patients who changed their therapy to splenectomy due to intolerable side-effects or bleeding symptoms were counted as both treatment failures and splenectomies. A secondary analysis excluding patients who discontinued the study showed a similar trend in the reduction in splenectomy and treatment failure in the Nplate group compared to the SOC group. Only 1 percent of Nplate patients (2/157) underwent a splenectomy compared with 19 percent of SOC patients (15/77). Additionally, 5 percent of Nplate patients (8/157) experienced treatment failure compared to 12 percent of SOC patients (9/77). The study also showed that the safety profile was comparable between the Nplate group and the group receiving the SOC. The safety analyses included all patients who received greater than or equal to 1 dose of Nplate or one type of SOC for ITP. Bleeding events with grade greater than or equal to 3 severity were reported by 8 percent of patients (6/75) in the SOC group, compared with 3 percent in the Nplate group (5/154). About the Study In total, 234 patients enrolled in this study, which assessed the efficacy and safety of Nplate compared to the medical SOC in adult patients with chronic ITP. SOC treatments were prescribed by the investigator according to standard institutional practices or therapeutic guidelines; the only treatments not allowed were investigational agents (rituximab was allowed) or other thrombopoietic agents. Adverse events (AEs) were experienced by 92 percent of patients receiving the SOC (69/75) and by 95 percent of patients (146/154) receiving Nplate. The most common AEs in the SOC group were epistaxis (23 percent), nasopharyngitis (19 percent), and contusion (19 percent); in the Nplate group the most common AEs were headache (35 percent), fatigue (27 percent), and nasopharyngitis (23 percent). Treatment-related serious AEs were reported by 8 percent of SOC (6/75) and 5 percent of Nplate patients (7/154). About Adult Chronic ITP In patients with chronic ITP, platelets - or blood elements needed to prevent bleeding - are destroyed by the patient's own immune system. Low platelet counts leave adult ITP patients open to sudden serious bleeding events. The risk for serious bleeding events can increase when platelet counts drop to less than 30,000 platelets per microlitre; normal counts range from 150,000 to 400,000 platelets per microlitre. ITP has historically been considered a disease of platelet destruction although recent data suggest that the body's natural platelet production processes in chronic ITP are unable to compensate for low levels of platelets in the blood. Increasing the rate of platelet production may address low platelet levels associated with ITP. Currently available treatments (e.g., corticosteroids, immunoglobulins and others) have limited application due to poor tolerability or transient effects. Surgical therapy (removal of the spleen) is also available to adult patients with chronic ITP, but does not work in all cases. Currently, there are approximately 140,000 treated chronic ITP patients in Europe (EU) and the United States (U.S.). Chronic ITP affects about twice as many adult women as men. About Nplate In Europe, Nplate is indicated for the treatment of splenectomised adult chronic immune (idiopathic) thrombocytopenic purpura (ITP) patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Nplate may be considered as a second-line treatment for adult non-splenectomised ITP patients for whom surgery is contra-indicated. Nplate, a thrombopoietin (TPO) mimetic, is a novel engineered therapeutic fusion protein with attributes of both peptides and antibodies, but is distinct from each. Nplate works similarly to TPO, a natural protein in the body. Nplate stimulates the TPO receptor, which is necessary for growth and maturation of bone marrow cells that produce platelets. Nplate was the first platelet producer approved for chronic ITP by the regulatory bodies in Australia, the EU, Canada, and the U.S., and is under review in Switzerland. Nplate also has received orphan designation for chronic ITP in the U.S. (2003), the EU (2005), Switzerland (2005) and Japan (2006). Nplate is the first treatment specifically developed for chronic ITP. It is also being investigated for potential use in paediatric ITP, myelodysplastic syndromes (MDS), and chemotherapy-induced thrombocytopenia (CIT). 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 disorder, 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. 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