Patients received Nplate® within 6 months of diagnosis, right after insufficient response to steroids[1,2]

Study design in newly diagnosed/persistent ITP (N = 75)[1-4]

Nplate® was studied in a 52-week, open-label, single-arm, phase 2 trial of adults with ITP for ≤ 6 months who had an insufficient response (platelet count ≤ 30 x 10^9/L) to first-line treatment, including corticosteroids.[‡]

- Nplate® was initiated at 1 mcg/kg and adjusted to achieve a platelet count ≥ 50 x 10^9/L to < 200 x 10^9/L[§]
- At the end of the 52-week treatment period, patients who had not entered remission, were still receiving Nplate®, and had a platelet count ≥ 50 x 10^9/L had their dose tapered by 1 mcg every 2 weeks, as long as weekly platelet counts remained ≥ 50 x 10^9/L

Primary endpoint:
Cumulative number of months in which a patient achieved a median platelet count ≥ 50 x 10^9/L

Select secondary endpoint:
Rate of remission, defined as maintaining every platelet count at ≥ 50 x 10^9/L for at least 6 months without any ITP treatment

The lack of a placebo control group prevents determination of remission rates without Nplate®.[2]

PRIMARY ENDPOINT RESULT

***Sustained response:** 61% of patients sustained platelet counts ≥ 50 x 10^9/L for ≥ 11 months during the treatment period[2]*

*Nplate® was initiated following a platelet count ≤ 30 x 10^9/L at any time during the 4-week screening period. Nplate® was initiated within 6 months of ITP diagnosis.[1,2]
†Treatment-free remission was a secondary endpoint defined as maintaining every platelet count at ≥ 50 x 10^9/L for at least 6 months in the absence of any ITP treatment, and occurred in 32% of patients.[1,2]
‡First-line treatments could have also included immunoglobulins, anti-D immunoglobulin, or vinca alkaloids.[2]
§Adjustments were made following the recommended dosage regimen (Section 2.1 of the Nplate® Prescribing Information).
ITP, immune thrombocytopenia.

INDICATION

Nplate® is a thrombopoietin receptor agonist indicated for the treatment of thrombocytopenia in adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Nplate® is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP. Nplate® should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. Nplate® should not be used in an attempt to normalize platelet counts.

IMPORTANT SAFETY INFORMATION

Risk of Progression of Myelodysplastic Syndromes to Acute Myelogenous Leukemia

- In Nplate® (romiplostim) clinical trials of patients with myelodysplastic syndromes (MDS) and severe thrombocytopenia, progression from MDS to acute myelogenous leukemia (AML) has been observed.
- Nplate® is not indicated for the treatment of thrombocytopenia due to MDS or any cause of thrombocytopenia other than ITP.

Please see full Prescribing Information and Medication Guide.

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Clinical trial results demonstrated that treatment-free remission is possible with Nplate® (romiplostim)[1,2]

~1 out of 3*
patients achieved treatment-free remission (n= 24/75) [1,2]

- Nplate® was used right after insufficient response to steroids[1]
- Nplate® maintained every platelet count at ≥ 50 x 10^9/L for at least 6 months without any ITP treatment[1]
- 27 weeks was the median time to onset of treatment-free remission (range, 6-57) [1,2]

In a post hoc subgroup analysis of the newly diagnosed ITP patients (<3 months) and persistent ITP patients (≥3–≤12 months): 38% of the newly diagnosed patients and 23% of the persistent patients achieved treatment-free remission respectively*[5]

*Post hoc subgroup analysis was performed on newly diagnosed (n=45) and persistent ITP patients (n=30) from the same phase 2 clinical trial. The remission rate in each subgroup was not a study objective and was not powered to assess efficacy.[5]

IMPORTANT SAFETY INFORMATION (cont'd)

Thrombotic/Thromboembolic Complications

- Thrombotic/thromboembolic complications may result from increases in platelet counts with Nplate® use. Portal vein thrombosis has been reported in patients with chronic liver disease receiving Nplate®.
- To minimize the risk for thrombotic/thromboembolic complications, do not use Nplate® in an attempt to normalize platelet counts. Follow the dose adjustment guidelines to achieve and maintain a platelet count of ≥ 50 x 10^9/L.

Loss of Response to Nplate®

- Hyporesponsiveness or failure to maintain a platelet response with Nplate® should prompt a search for causative factors, including neutralizing antibodies to Nplate®.
- To detect antibody formation, submit blood samples to Amgen (1-800-772-6436). Amgen will assay these samples for antibodies to Nplate® and thrombopoietin (TPO).
- Discontinue Nplate® if the platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the highest weekly dose of 10 mcg/kg.

Adverse Reactions

- In the placebo-controlled trials, headache was the most commonly reported adverse drug reaction, occurring in 35% of patients receiving Nplate® and 32% of patients receiving placebo. Adverse drug reactions with ≥ 5% higher patient incidenc versus placebo were Arthralgia (26%, 20%), Dizziness (17%, 0%), Insomnia (16%, 7%), Myalgia (14%, 2%), Pain in Extremity (13%, 5%), Abdominal Pain (11%, 0%), Shoulder Pain (8%, 0%), Dyspepsia (7%, 0%), and Paresthesia (6%, 0%).
- The safety profile of Nplate® was similar across patients, regardless of ITP duration. The following adverse reactions (at least 5% incidence and at least 5% more frequent with Nplate® compared with placebo or standard of care) occurred in Nplate® patients with ITP duration up to 12 months: bronchitis, sinusitis, vomiting, arthralgia, myalgia, headache, dizziness, diarrhea, upper respiratory tract infection, cough, nausea and oropharyngeal pain. The adverse reaction of thrombocytosis occurred with an incidence of 2% in adults with ITP duration up to 12 months.

Nplate® administration may increase the risk for development or progression of reticulin fiber formation within the bone marrow. This formation may improve upon discontinuation of Nplate®. In a clinical trial, one patient with ITP and hemolytic anemia developed marrow fibrosis with collagen during Nplate® therapy.

Please see full Prescribing Information and Medication Guide.

References: 1. Nplate® (romiplostim) prescribing information, Amgen. **2.** Newland A, Godeau VP, Priego V, et al. Remission and platelet responses with romiplostim in primary immune thrombocytopenia: final results from a phase 2 study. *Br J Haematol*. 2016;172(2):262-273. **3.** Newland A, Godeau B, Priego V, et al. Remission and platelet responses with romiplostim in primary immune thrombocytopenia: final results from a phase 2 study. *Br J Haematol*. 2016;172(Suppl):1-4. **4.** Data on File, Amgen; Clinical Study Report **5.** Newland AC. Viallard J, Lopez Fernandez MF, et al. Romiplostim for the Treatment of Adult Patients with Newly Diagnosed or Persistent Immune Thrombocytopenia: Subgroup Analysis from a Phase 2 Study. American Society for Hematology. 2021;311. Abstract 3157.

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