

Study of Ianalumab Versus Placebo in Addition to First-line Corticosteroids in Primary Immune Thrombocytopenia (ITP)

Last Update: Apr 18, 2025

A Phase III, Randomized, Double-blind Study of Ianalumab (VAY736) Versus Placebo in Addition to First-line Corticosteroids in Primary Immune Thrombocytopenia (VAYHIT1)

ClinicalTrials.gov Identifier:

[NCT05653349](#)

Novartis Reference Number: CVAY736I12301

[See if you Pre-qualify](#)

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to evaluate the effect of two different doses of Ianalumab versus placebo in addition to first-line corticosteroids in maintaining platelet count ≥ 30 G/L in adult participants with primary ITP. This is a multi-center, randomized, double-blind Phase 3 study to assess the efficacy and safety of two different doses of Ianalumab compared to placebo in adults with primary ITP (platelets count < 30 G/L) who require first-line standard-of-care corticosteroids.

After completion of the screening period, the participants will enter the randomized treatment period (Ianalumab/placebo with standard of care corticosteroids).

After the treatment period, all participants will enter the follow-up period to be monitored for efficacy and safety or safety only depending on how they respond to the study treatment.

Condition

Primary Immune Thrombocytopenia (ITP)

Phase

Phase3

Overall Status

Recruiting

Number of Participants

225

Start Date

Mar 06, 2023

Completion Date

Dec 18, 2028

Gender

All

Age(s)

18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Corticosteroids

Oral or parental (if clinically justified)

Biological

Ianalumab

Intravenous infusion, prepared from concentrate solution

Drug

Placebo

Intravenous infusion, prepared from matching placebo

Eligibility Criteria

Inclusion Criteria:

- * Signed informed consent prior to participation in the study.
- * Male or female participants aged 18 years and older on the day of signing informed consent
- * Primary ITP diagnosed within 3 months before initiating first-line ITP therapy (corticosteroids, IVIG)
- * Platelet count below 30 G/L before starting any first-line ITP therapy (corticosteroids, IVIG)
- * Response (platelet count ≥ 50 G/L) to corticosteroids (+/- IVIG) at any time prior to randomization. Note: Platelet count measured within 7 days of platelet transfusion will not be considered as response.

Key Exclusion Criteria:

- * Evans syndrome or any other cytopenia (patients with low grade anemia related to bleeding or iron deficiency are eligible)
- * Current life-threatening bleeding
- * Previous ITP treatment, including splenectomy, except for corticosteroids and/or IVIG initiated as first-line therapy for up to 28 days before randomization and rescue corticosteroids and/or IVIG given prior to confirmed diagnosis of primary ITP .
- * Prior use of B-cell depleting therapy (e.g., rituximab).
- * Absolute neutrophil count below 1.0 G/L at randomization
- * Participants with concurrent coagulation disorders and/or receiving anti-platelet or anticoagulant medication with an exemption of low dose of acetylsalicylic acid

Other protocol-defined Inclusion/Exclusion may apply.

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