Two-period Crossover Study to Demonstrate the Comparability of Pharmacokinetics of Subcutaneous Ianalumab Between 2mL Auto-injector/2mL PFS with1mL Pre-filled Syringe in Adult Participants With Autoimmune Disease

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A Randomized, Two-period Crossover Study to Demonstrate the Comparability of Pharmacokinetics of Subcutaneous Ianalumab Between 2mL Auto-injector/2mL Pre-filled Syringe With 1 mL Pre-filled Syringe in Adult Participants With Autoimmune Disease
ClinicalTrials.gov Identifier:
NCT06293365
Novartis Reference Number:CVAY736A2202
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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 demonstrate the comparability of ianalumab exposure following the subcutaneous (s.c.) administration of one injection of 300 mg/2 mL auto-injector (AI) versus two injections of 150 mg/1 mL pre-filled syringe (PFS), and to evaluate the safety and tolerability of ianalumab following the s.c. administration of both devices in participants with rheumatoid arthritis (RA), Sjögren's disease (SjD), or systemic lupus erythematosus (SLE).

A second optional cohort may be included with the objective of demonstrating the comparability of pharmacokinetics of ianalumab between 1 x 2 mL Pre-filled Syringe (PFS) and 2 x 1 mL PFS. The study consists of the following periods:

Screening period (up to 4 weeks):

Following the signing of the informed consent, participants will be assessed for eligibility during this period of up to 4 weeks.

Treatment Period 1 + Treatment Period 2, (Week 0 to Week 24):

After completion of the screening period, eligible participants will be randomized at the Baseline visit (Week 0) to one of the 2 treatment sequences (treatment switch at Week 12) in a ratio of 1:1 described below:

* Cohort 1:

* Sequence 1: ianalumab 300 mg s.c. (2 x 1 mL PFS) monthly + SoC in Treatment Period 1 and ianalumab

300 mg s.c. (1 x 2 mL AI) monthly + SoC in Treatment Period 2
* Sequence 2: ianalumab 300 mg s.c. (1 x 2 mL AI) monthly + SoC in Treatment Period 1 and ianalumab 300 mg s.c. (2 x 1 mL PFS) monthly + SoC in Treatment Period 2
* Cohort 2 (Optional):

* Sequence 1: ianalumab 300 mg s.c. (2 x 1 mL PFS) monthly + SoC in Treatment Period 1 and ianalumab 300 mg s.c. (1 x 2 mL PFS) monthly + SoC in Treatment Period 2
* Sequence 2: ianalumab 300 mg s.c. (1 x 2 mL PFS) monthly + SoC in Treatment Period 1 and ianalumab 300 mg s.c. (2 x 1 mL PFS) monthly + SoC in Treatment Period 2 In addition, within each sequence, participants will be further randomized to one of the predetermined injection sites with equal allocation, resulting in a total randomization combination of four (2 sequences x 2 injection sites) for Cohort 1 and six (2 sequences x 3 injection sites) for Cohort 2, respectively.

Extended Treatment period (Week 24 to Week 72): After completion of Week 24 assessment, all participants (who did not discontinue during treatment period) will have the option to enter the extended treatment period to receive ianalumab 300 mg s.c. (Cohort 1: 2 mL AI; Cohort 2: 2 mL PFS) monthly up to Week 68. The end of treatment (EOT) visit will be performed 4 weeks after the last study treatment administration, i.e., at Week 72.

Mandatory Post-Treatment safety follow-up period (from Week 72 to Week 88): Participants who completed the last study treatment or prematurely discontinued from study treatment will enter the post-treatment safety follow-up period.

Conditional Post-Treatment safety follow-up period (from Week 88 to Week 176) Post-treatment follow-up will be performed until B-cell recovery or up to 2 years. B-cell recovery is defined when CD19+ B-cell counts return to \>= 50 cells/µL or \>= 80% of baseline value, whichever occurs earlier.

Condition
Sjögrens Disease, Systemic Lupus Erythematosus, Rheumatoid Arthritis
Phase
Phase2
Overall Status
Recruiting
Number of Participants
140
Start Date
Jul 10, 2024
Completion Date
Feb 08, 2029
Gender
All
Age(s)
18 Years - 70 Years (Adult, Older Adult)

Interventions

Biological

VAY736 1ml PFS

Solution for injection.

Biological

VAY736 2 ml PFS

Solution for injection
Biological

VAY736 2ml AI

Solution for injection.

Eligibility Criteria

Key Inclusion criteria:

* Signed informed consent must be obtained before any assessment is performed.
* Male and female patients aged 18 years to 70 years (inclusive).
* Body weight at least 35 kg and not more than 150 kg and must have a body mass index (BMI) within the range of 18 - 35 kg/m2. BMI = Body weight (kg) / \[Height (m)\]2 at screening.
* Diagnosed with RA, SjD and/or SLE as determined by the investigator.
* Have active disease (RA, SjD or SLE) that may benefit from B-cell depletion therapy, as determined by the investigator.
* Participants currently receiving protocol-allowed SoC should be on stable doses of SoC medications for 4 weeks prior to first dosing of study treatment.
* Ability to communicate well with the investigator, understand and agree to comply with the requirements of the study.

Key Exclusion criteria:

* Use of prohibited therapies.
* Active viral, bacterial or other infections requiring systemic treatment at the time of screening or baseline or history of recurrent clinically significant infection.
* Plans for administration of live vaccines during the study period.
* Uncontrolled co-existing serious disease.
* Pregnant or nursing (lactating) women.
* Women of child-bearing potential (WOCBP), defined as all women physiologically capable of becoming pregnant, refusing or unable to use highly effective methods of contraception while on study treatment and for 6 months after stopping of study drug.
* US (and other countries, if locally required): sexually active males unless using barrier protection during intercourse with women of child-bearing potential while taking study treatment.

Other protocol-defined inclusion/exclusion criteria may apply.

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