

A Randomized, Double-blind 2-arm NEPTUNUS Extension Study to Assess the Long-term Safety and Efficacy of Ianalumab in Patients With Sjogrens Syndrome.

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ClinicalTrials.gov Identifier:

[NCT05985915](#)

Novartis Reference Number: CVAY736A2301E1

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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 measure the long-term safety and tolerability of Ianalumab in participants with Sjogrens syndrome who have previously completed treatment from one of two NEPTUNUS 1 year core studies (CVAY736A2301 \[NCT05350072\] or CVAY736A2302 \[NCT05349214\]).

- * The study treatment is Ianalumab 300 mg in a 2 mL pre-filled syringe (PFS) or in a 2 mL autoinjector (AI) for injection. All participants will receive Ianalumab either monthly or every 3 months.
- * The treatment duration will be 3 years with an additional up to 2-year safety follow-up. The total duration of this extension study will be up to 5 years.
- * The visit frequency will be monthly during both the treatment period and mandatory follow-up, and then less frequently during the subsequent conditional follow-up.

Treatment of interest: The randomized treatment (Ianalumab) will be received monthly or every 3 months. Participants assigned to treatment every 3 months will receive placebo every month between the Ianalumab doses to maintain blinding.

Number of Participants: Approximately 600 participants from the NEPTUNUS core studies will be rolled over into the extension study.

Treatment Groups: There will be no screening period in this trial. From Week 48 of the NEPTUNUS core study, participants will be given the opportunity to consent to this extension study. From Week 52 of the NEPTUNUS core studies (i.e., Day 1 in the extension study), eligible participants will be assigned to either one of the treatment regimens:

- * Ianalumab 300 mg monthly or
- * Ianalumab 300 mg once every 3 months

Participants receiving placebo in either of the NEPTUNUS core studies will be randomized 1:1 to receive ianalumab 300 mg monthly or every 3 months starting from Week 60 and participants receiving ianalumab in either of the NEPTUNUS core studies will continue the same treatment in the extension study.

Ianalumab will be given as a subcutaneous injection from a 2 mL pre-filled syringe or a 2 mL autoinjector. Participants will be given the opportunity to self-inject at home on some visits after receiving training. The primary purpose of this 3-year treatment extension study is the continued evaluation of the safety and tolerability of treatment with ianalumab 300 mg monthly or every 3 months. An additional purpose is to explore the long-term efficacy of both dosing regimens of ianalumab 300 mg.

Trial Design: This is a multicenter, randomized, double-blind, phase 3 study to assess the long-term safety and tolerability of four treatment regimens of ianalumab in participants with Sjogrens syndrome who have taken part in and completed one of two NEPTUNUS core studies, NEPTUNUS-1 (CVAY736A2301) or NEPTUNUS-2 (CVAY736A2302). There will be no screening period in this trial. From week 48 of the NEPTUNUS core study, participants will be given the opportunity to consent to this extension study. Eligible participants will continue their assigned treatment to receive ianalumab 300 mg either monthly or every 3 months for up to 3 additional years of treatment beyond the 1-year core study period. After the treatment period, all participants will enter a follow-up period to be monitored for at least 20 weeks and then a conditional (if B-cell recovery criteria have not been met) follow-up period. The total post treatment follow-up period is up to 2 years.

Study Population: Participants with Sjogrens syndrome who have completed treatment in one of two NEPTUNUS core studies.

Study treatment assignment method: Participants randomized to ianalumab 300 mg monthly or every 3 months in one of the NEPTUNUS core studies will continue their assigned treatment. Participants randomized to placebo in the NEPTUNUS core studies will be randomized in a 1:1 ratio to either ianalumab 300 mg monthly or every 3 months.

Participants randomized to ianalumab 300 mg every 3 months will receive placebo (a dummy treatment) once monthly between doses.

Committees: An independent Data Monitoring Committee (DMC) will be utilized for safety review throughout the study. A steering committee will be formed to ensure overview of the study conduct.

Condition

Sjogrens Syndrome

Phase

Phase3

Overall Status

Recruiting

Number of Participants

600

Start Date

Oct 27, 2023

Completion Date

Jul 18, 2030

Gender

All

Age(s)

18 Years - 75 Years (Adult, Older Adult)

Interventions

Drug

Ianalumab (VAY736)

Ianalumab 300 mg / 2 mL, PFS or AI, monthly or every 3 months, solution for injection for subcutaneous use

Other

Placebo

Placebo 0 mg/2 mL PFS or AI, once monthly between doses of Ianalumab 3 monthly , solution for injection for subcutaneous Use

Eligibility Criteria

Inclusion Criteria:

1. Signed informed consent prior to participation in the extension study.
2. Participants must have participated in either one of the two NEPTUNUS core studies, CVAY736A2301 or CVAY736A2302, and must have completed the entire treatment up to Week 48 without treatment discontinuation in core NEPTUNUS studies.
3. In the judgement of the Investigator, participants must be expected to clinically benefit from continued Ianalumab therapy.

Exclusion Criteria:

1. Use of therapies excluded by the NEPTUNUS-1 and NEPTUNUS-2 study protocols (see NEPTUNUS studies protocols exclusion criteria in Section 5.2 for details).
2. Plans for administration of live vaccines during the study period.
3. Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive human Chorionic Gonadotropin (hCG) laboratory test.
4. Women of child-bearing potential (WOCBP), defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception while taking study treatment during dosing and for 6 months after stopping of investigational drug. Highly effective contraception methods include:

* Total abstinence (when this is in line with the preferred and usual lifestyle of the participant. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception.

* Female bilateral tubal ligation, female sterilization (have had surgical bilateral oophorectomy with or without hysterectomy) or total hysterectomy at least six weeks before taking study treatment. In case of oophorectomy alone, only when the reproductive status of the woman has been confirmed by follow up hormone level assessment.

* Male sterilization (at least 6 months prior to screening). For female participants on the study, the vasectomized male partner should be the sole partner for that participant.

* Use of oral (estrogen and progesterone), injected, or implanted hormonal methods of contraception or placement of an intrauterine device (IUD) or intrauterine system (IUS), or other forms of hormonal contraception that have comparable efficacy (failure rate < 1%), for example hormone vaginal ring or

transdermal hormone contraception.

In case of use of oral contraception women should have been stable on the same pill for a minimum of 3 months before taking study treatment.

Contraception should be used in accordance with locally approved prescribing information of concomitant medications administered.

Women are considered post-menopausal if they have had 12 months of natural (spontaneous) amenorrhea with an appropriate clinical profile (e.g., age-appropriate history of vasomotor symptoms). Women are considered of not child-bearing potential if they are post-menopausal or have had surgical bilateral oophorectomy (with or without hysterectomy), total hysterectomy or bilateral tubal ligation at least six weeks ago. In the case of oophorectomy alone, only when the reproductive status of the woman has been confirmed by follow-up hormone level assessment is she considered not of child-bearing potential.

If local regulations deviate from the contraception methods listed above to prevent pregnancy, local regulations apply and will be described in the informed consent form (ICF).

5. United States (and other countries, if male contraception is locally required): Sexually active males, unless they agree to use barrier protection during intercourse with a woman of child-bearing potential, while taking study treatment. As condom use alone has a reported failure rate exceeding 1% per year, it is recommended that female partners of male study participants use a second method of birth control. Although ianalumab is not teratogenic and/or genotoxic, and not transferred to semen, male contraception is required, as requested by FDA.

Globally, for all sexually active males, contraception should be used in accordance with the locally approved prescribing information of concomitant medications administered.

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