Three-arm Study to Assess Efficacy and Safety of Ianalumab (VAY736) in Patients With Active Sjögren's Syndrome

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Main Information

Primary registry identifying number
LBCTR2022065051

Protocol number
CVAY736A2302

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency

Primary sponsor
Novartis Pharmaceuticals

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
09/12/2022

Date of registration in national regulatory agency

Public title
Three-arm Study to Assess Efficacy and Safety of Ianalumab (VAY736) in Patients With Active Sjögren's Syndrome

Acronym

Scientific title
A Randomized, Double-blind, Placebo Controlled, 3-arm Multicenter Phase 3 Study to Assess the Efficacy and Safety of Ianalumab in Patients With Active Sjogren's Syndrome

Acronym
NEPTUNUS-2

Brief summary of the study: English
A randomized, double-blind, placebo controlled, 3-arm multicenter phase 3 study to assess the efficacy and safety of ianalumab in patients with active Sjögren's syndrome

Brief summary of the study: Arabic
لتقييم فعاليّة3 مجموعات، متعددة المراكز في المرحلة 3دراسة عشوائيّة التوزيع، مزدوجة التعمية، مرتكزة على المقارنة بدواء وهمي، من وسلامة دواء إيانالوماب لدى المرضى المصابين بمتلازمة شوغرن النشطة

Health conditions/problem studied: Specify
Sjogren Syndrome

Interventions: Specify
- Biological: VAY736
  ianalumab s.c.

- Other: Placebo
  placebo s.c.

Key inclusion and exclusion criteria: Inclusion criteria
- Signed informed consent must be obtained prior to participation in the study
- Women and men ≥ 18 years of age
- Classification of Sjögren's syndrome according to the ACR/EULAR 2016 criteria

- Time since diagnosis of Sjögren's of ≤ 7.5 years at screening
Positive anti-Ro/SSA antibody at screening
Patients negative for anti-Ro/SSA antibody are eligible, if they have a positive salivary gland biopsy confirmed by central expert review
- Enrollment of anti-Ro/SSA-negative patients will be limited up to ≤10% of the study population
- Screening ESSDAI score of ≥ 5 within the following 8 domains: constitutional, lymphadenopathy, glandular, articular, cutaneous, renal, hematological and biologic.
- Stimulated whole salivary flow (sSF) rate of ≥ 0.05 mL/min at screening
- Ability to communicate well with the Investigator, understand and agree to comply with the requirements of the study
- Patients taking hydroxychloroquine (≤ 400 mg/day), methotrexate (≤ 25 mg/week) or azathioprine (≤ 150 mg/day) alone or in combination, are allowed to continue their medication, and must have been on a stable dose for at least 30 days prior to randomization.
- Patients taking systemic corticosteroids have to be on a stable dose of ≤ 10 mg/day predniso(lo)ne or equivalent for at least 30 days before randomization.
- Patients taking
disease-modifying antirheumatic drugs (DMARDs) other than specifically allowed in inclusion criterion #9 or
the following Traditional Chinese Medicines: Total glucoside of peony (TGP) or Tripterium glycosides (TG)
- must discontinue these medications at least 30 days prior to randomization, except for leflunomide, which has to be discontinued for 8 weeks prior to randomization unless a cholestyramine wash-out has been performed.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

- Presence of another autoimmune rheumatic disease that is active and constitutes the principal illness
- Use of other investigational drugs within 5 half-lives of enrollment, or within 30 days or until the expected pharmacodynamic effect has returned to baseline, whichever is longer3. Prior treatment with ianalumab
- Prior use of a B-cell depleting therapy other than ianalumab within 36 weeks prior to randomization or as long as B-cell count is <50 cells/µL
- Prior treatment with any of the following within 6 months prior to randomization:
iscalimab, belimumab , abatacept, anti-tumor necrosis factor alpha biologic agents, immunoglobulins plasmapheresis; i.v. or oral cyclophosphamide and mycophenolate mofetil, i.v. or oral cyclosporine A; any other immunosuppressants (e.g., JAK inhibitors or other kinase inhibitors) unless explicitly allowed by protocol
- Use of corticosteroids (predniso(lo)ne or equivalent corticosteroid) at dose >10 mg/day
- Any one of the following laboratory values at screening:
Hemoglobin levels < 8.0 g/dL
White blood cells (WBC) count < 2.0 x 10E3/µL
Platelet count < 80 x 10E3/µL
Absolute neutrophil count (ANC) < 0.8 x 10E3/µL
- Active viral, bacterial or other infections requiring systemic treatment at the time of screening or randomization, or history of recurrent clinically significant infection or of bacterial infections with encapsulated organisms
- History of hypersensitivity to any of the study drugs or its excipients or to drugs of similar chemical classes (e.g., mAb of IgG1 class) or to any of the constituents of the study drug formulation (sucrose, L-histidine hydrochloride/ L-histidine, polysorbate 20)
- History of major organ, hematopoietic stem cell or bone marrow transplant
- Required regular use of medications known to cause dry mouth/eyes as a regular and major side effect, and which have not been on a stable dose for at least 30 days prior to Screening, or any anticipated change in the treatment regimen during the course of the study.
- Use of topical ocular prescription medications (excluding artificial tears, gels, lubricants) that have not been on a stable dose for at least 90 days prior to randomization, or any anticipated change in the treatment regimen during the course of the study
- Receipt of live/attenuated vaccine within a 4-week period prior to randomization
- History of primary or secondary immunodeficiency, including a positive human immunodeficiency virus (HIV) test result
- History of malignancy of any organ system (other than localized basal cell carcinoma of the skin or in situ cervical cancer or Sjögren's related lymphoma), treated or untreated, within the past 5 years, regardless of whether there is evidence of local recurrence or metastases.
- History of sarcoidosis
- Any surgical, medical (e.g., uncontrolled hypertension, heart failure or diabetes mellitus), psychiatric or additional physical condition that the Investigator feels may jeopardize the patient in case of participation in this study
- Chronic infection with hepatitis B (HBV) or hepatitis C (HCV). Positive serology for hepatitis B surface antigen (HBsAg) excludes the subject.
- Evidence of active tuberculosis (TB) infection (after anti-TB treatment, patients with history of or latent TB may become eligible according to national guidelines)
- Pregnant or nursing (lactating) women,
- Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception while on study treatment and for 6 months after stopping of investigational medication.
- Patients with a known history of non-compliance to medication, or who were unable or unwilling to complete PRO questionnaires, or who are unable or unwilling to use the device for collection of PROs.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope
Therapy

Trial scope: Specify scope
N/A

Study design: Allocation
Randomized controlled trial

Study design: Masking
Blinded (masking used)

Study design: Control
Placebo

Study phase
3

Study design: Purpose
Treatment

Study design: Specify purpose
N/A

Study design: Assignment
Parallel

Study design: Specify assignment
N/A

IMP has market authorization
No

IMP has market authorization: Specify

Name of IMP
Ianalumab

Year of authorization

Month of authorization

Type of IMP
Immunological

Pharmaceutical class
human IgG1 monoclonal antibody

Therapeutic indication
Active Sjogren's Syndrome

Therapeutic benefit
Treatment

Study model
N/A

Study model: Explain model
N/A

Study model: Specify model
N/A

Time perspective
N/A

Time perspective: Explain time perspective
N/A

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Biospecimen description

Samples with DNA**

Samples will be shipped to Q2 solutions central lab

Target sample size

5

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

22/02/2023

Date of study closure: Type

Anticipated

Date of study closure: Date

08/03/2028

Recruitment status

Recruiting

Recruitment status: Specify

Date of completion

IPD sharing statement plan

Yes

IPD sharing statement description

Novartis is committed to sharing access to patient-level data and supporting clinical documents from eligible studies with qualified external researchers. Requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to protect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT05349214?term=CVAY736A2302&draw=2&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
clinicaltrials.gov	NCT05349214

Sources of Monetary or Material Support

Name
Novartis Pharmaceuticals

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Nelly Ziade	Beirut	Lebanon	+96170973214	nellziade@yahoo.fr	Hotel dieu de France Hospital
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Public	Imad Uthman	Beirut	Lebanon	+9613379098	iuthman@aub.edu.lb	American University of Beirut Medical Center

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel dieu de France Hospital	Nelly Ziade	Rheumatology	Approved
American University of Beirut Medical Center	Imad Uthman	Rheumatology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	03/05/2022	Nancy Alam	nancy.alam@usj.edu.lb	+9611421000 ext. 2335
American University of Beirut Medical Center	23/11/2022	Rami Mahfouz	rm11@aub.edu.lb	+9611350 000 ext:5445

Countries of Recruitment

Name
Lebanon
Canada
Hungary

Health Conditions or Problems Studied

Condition	Code	Keyword
Active Sjögren's syndrome	Other systemic involvement of connective tissue (M35)	Sjögren's syndrome

Interventions

Intervention	Description	Keyword
Consenting, IMP administration, Laboratory testing	Consenting, IMP administration, Laboratory testing	Consenting, IMP administration, Laboratory testing

Primary Outcomes

Name	Time Points	Measure
Efficacy	48 weeks	Change from baseline in EULAR Sjögren Syndrome Disease Activity Index (ESSDAI) score at Week 48 as compared to placebo

Key Secondary Outcomes

Name	Time Points	Measure
Efficacy	48 weeks	Proportion of patients achieving ≥3 points reduction from baseline in ESSDAI score at Week 48
Efficacy	48 weeks	Proportion of patients achieving ESSDAI<5 at Week 48
Efficacy	24 weeks	Proportion of patients achieving ESSDAI<5 at Week 48
Efficacy	48 weeks	Change from baseline in stimulated whole salivary flow rate at Week 48
Efficacy	48 weeks	Change from baseline in Physician's Global Assessment (PhGA) of disease activity at Week 48
Efficacy	48 weeks	Change from baseline in Patient's Global Assessment (PaGA) of disease activity at Week 48
Efficacy	48 weeks	Change from baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) score at Week 48
Efficacy	48 weeks	Proportion of patients achieving meaningful improvement in the Sjogren's Syndrome Symptom Diary (SSSD) score at Week 48
Efficacy	48 weeks	Proportion of patients achieving ≥ 1 point or 15% reduction from baseline in EULAR Sjögren Syndrome Patient Reported Index (ESSPRI) at Week 48

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files