A Phase 2a, Double-Blind, Randomized, Placebo-Controlled Study of Ravagalimab in Subjects with Moderately to Severely Active Primary Sjogren's Syndrome.

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To evaluate the safety and efficacy of ravagalimab vs placebo for the treatment of primary Sjogren's syndrome (pSS) in subjects with moderately to severely active primary Sjogren's syndrome (pSS).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON48111

Source
ToetsingOnline

Brief title
M19-956

Condition

- Autoimmune disorders

Synonym
Primary Sjogrens Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: AbbVie Deutschland GmbH & Co. KG

Source(s) of monetary or material Support: AbbVie

Intervention

Keyword: Primary Sjogren Syndrome

Outcome measures

Primary outcome

The change from Baseline (CFB) in European League Against Rheumatism (EULAR) Sjogren's Syndrome Disease Activity Index (ESSDAI) at Week 24.

Secondary outcome

The secondary endpoints including the following:

• CFB (Change from baseline) in EULAR Sjogren's Syndrome Disease Activity Index (ESSDAI) at Weeks 4, 8, 12, and 16

• CFB in EULAR Sjogren's Syndrome Patient Reported Index (ESSPRI) at Weeks 4, 8, 12,16, and 24

• CFB in tender joint count and swollen joint count (68/66) at Weeks 4, 8, 12, 16, and 24

• CFB in salivary flow, unstimulated at Weeks 4, 8, 12, 16, and 24

• CFB in salivary flow, stimulated, at Weeks 4, 8, 12, 16, and 24

• CFB in lacrimal flow (Schirmer's test of ocular function) at Weeks 4, 8, 12, 16, and 24

• CFB in tear break-up time at Weeks 4, 8, 12,16 and 24

• CFB in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) at Weeks 4, 8, 12, 16, and 24

Study description

Background summary

Sjogren's syndrome (SS) is a chronic, multisystem autoimmune disease characterized by lacrimal and salivary gland inflammation, with resultant dryness of the eyes and mouth and occasional glandular enlargement. In addition, a variety of systemic manifestations may occur; including fatigue, musculoskeletal symptoms, rashes, and internal organ (e.g., pulmonary, renal, hepatic, and neurologic) disease. Sjogren's syndrome may occur in isolation, primary Sjogren's syndrome (pSS), or in a secondary form, often associated with rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), or systemic sclerosis. Ravagalimab is an investigational drug being developed to help treat patients with inflammatory diseases like SS. This study will evaluate how well ravagalimab works within the body and how safe it is in patients with Primary SS (pSS).

Study objective

To evaluate the safety and efficacy of ravagalimab vs placebo for the treatment of primary Sjogren's syndrome (pSS) in subjects with moderately to severely active primary Sjogren's syndrome (pSS).

Study design

Randomised, double blind, parallel group, placebo controlled.

Intervention

Ravagalimab intravenous (IV) loading dose or IV placebo at baseline followed by subcutaneous (SC) ravagalimab or matching placebo.

Study burden and risks

• CFB in patient and physician global assessments using Numeric Rate Scale (NRS) at Week 4, 8, 12, 16, and 24
• CFB in anti-Sjogrens-syndrome-related-antigen A (Anti-SSA), anti-Sjogrens-syndrome-related-antigen B (Anti-SSB), antinuclear antibody (ANA) and rheumatoid factor (RF) at Weeks 4, 12, and 24
• CFB in high-sensitivity C-reactive protein (hsCRP), immunoglobulins M, G, and A, serum free light chains, C3, C4 and CH50 at Weeks 4, 8, 12, 16, and 24
• CFB in focus score of sub-labial gland biopsy at Week 24.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Adult male or female, between 18 and 75 years of age, inclusive, at time of the Screening.
• Primary Sjogren's syndrome (pSS) diagnosed according to the American College of Rheumatology (ACR)/EULAR 2016 Criteria.
• Lymphocyte focus score (local lymphocytic infiltrates) >=1 in sub labial salivary gland specimen. Subjects with biopsy obtained 24 months prior to Screening and meeting this criterion will be eligible but must have a sub labial biopsy obtained at the Baseline Visit. Subjects without a prior sub labial biopsy within 24 months of Screening will obtain a biopsy for a lymphocyte focus score at Screening.
• EULAR Sjögren's Syndrome Disease Activity Index (ESSDAI) >=5 at Screening and Baseline.

• EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) >= 6 at Screening and Baseline.

Exclusion criteria

1) Female subject who is pregnant, breastfeeding, or considering becoming pregnant during the study or for approximately 84 days.
2) Subjects must have discontinued all immunosuppressants (i.e., azathioprine , methotrexate (MTX), leflunomide (LEF), hydroxychloroquine (HCQ), chloroquine, sulfasalazine, mycophenolate mofetil, rituximab, other biologics, or JAK inhibitors), other than corticosteroids (equivalent to prednisone <= 10 mg/day), prior to the Baseline, with the following washout:
• HCQ must be discontinued >= 6 months prior to Baseline
• LEF must be discontinued >= 6 months prior to Baseline
• 1 year for rituximab OR 6 months if B cells have returned to pretreatment level or normal reference range (local laboratory) if pretreatment levels are not available;
• Discontinuation or modification of all other immunosuppressants must occur >= 4 weeks prior to Baseline or at least five times the mean terminal elimination half-life of the drug before undergoing the Baseline, whichever is longer.
3) Subject must not receive IV anti-infectives within 35 days prior to Baseline or oral/intramuscular (IM) anti-infectives within 14 days prior to the Baseline

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Will not start

Enrollment:	45
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Ravagalimab
Generic name:	ABBV-323

Ethics review

Approved WMO Date:	12-12-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-02-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-02-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-07-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2019-003131-31-NL
CCMO	NL71251.056.19

Study results

Date completed: 14-09-2021

Results posted: 22-09-2021

Summary results
Trial never started

First publication
14-09-2021