A Multicenter, Randomized, Dose-Blind, Phase 3 Long-Term Extension Study to Evaluate Continuous Safety and Efficacy of Litifilimab (BIIB059) in Adult Participants with Active Systemic Lupus Erythematosus.

Published: 05-10-2022
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This study has been transitioned to CTIS with ID 2023-505635-13-00 check the CTIS register for the current data. The Primary Objective of this Clinical Trial is to evaluate the long-term safety and tolerability of litifilimab in participants with...

Ethical review	Approved WMO
Status	Pending
Health condition type	Connective tissue disorders (excl congenital)
Study type	Interventional

Summary

ID

NL-OMON51320

Source
ToetsingOnline

Brief title
230LE306 "EMERALD"

Condition

- Connective tissue disorders (excl congenital)

Synonym
Lupus, Systemic Lupus Erythematosus

Research involving

Human

Sponsors and support

Primary sponsor: Biogen
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: BIIB059, SLE, Systemic Lupus Erythematosus

Outcome measures

Primary outcome

- Incidence of TEAEs - Number of Participants with Treatment Emergent Adverse

Events (TEAEs)

- Incidence of SAEs - Number of Participants with Serious Adverse Events (SAEs)

Secondary outcome

- Proportion of Participants who Achieved an Systemic Lupus Erythematosus

Responder Index (SRI)-4 Response by visit

- Proportion of Participants who Achieved a Joint-50 Response by visit

- Proportion of Participants who Achieved Cutaneous Lupus Erythematosus Disease

Area and Severity Index (CLASI)-50, CLASI-70,

and CLASI-90 Response by visit

- Proportion of Participants who Achieved a British Isles Lupus Assessment

Group based Composite Lupus Assessment (BICLA)

Response by visit

- Annualized Severe Safety of Estrogens in Systemic Lupus Erythematosus

National Assessment - Systemic Lupus Erythematosus

Disease Activity Index Flare Index (SFI) Flare Rate where severe flare is

defined using the SFI definition (Appendix B of the Protocol)

- Percentage of Time Spent in Lupus Low Disease Activity State (LLDAS)

- Proportion of participants with sustained LLDAS

- Duration of Sustained LLDAS as Defined by the Number of Visits in LLDAS up to

Week 180

- Annual Change From Baseline Value From the Parent Phase 3 Studies in Systemic

Lupus International Collaborating Clinics/American College of

Rheumatology Damage Index (SDI) Score

- Cumulative Exposure to OCS Over Time

- Percentage of Participants With OCS <=7.5 mg by visit

- Percentage of Participants With OCS <=5 mg up by visit

- Participant-reported outcome measures: LupusQoL, SF-36 (Acute Version),

EQ-5D-3L, FACIT-Fatigue, PHQ-9, WPAI:Lupus, and PtGA

- Change in standard laboratory parameters and ECG results

- Incidence of antibodies to litifilimab

Study description

Background summary

BIIB059 is a type of antibody (a substance that is made by the immune system) that has been developed in a lab to be used in people. The study drug has been developed to target certain cells that are thought to play a role in the development of lupus. It is hoped the study drug can improve symptoms in people who have SLE.

Earlier research studies have already looked at whether the study drug was safe for people with SLE, and whether it helped to control their symptoms. Based on the positive results from earlier studies, the researchers now want to know

whether the study drug works better when given for a longer period of time.

Study objective

This study has been transitioned to CTIS with ID 2023-505635-13-00 check the CTIS register for the current data.

The Primary Objective of this Clinical Trial is to evaluate the long-term safety and tolerability of litifilimab in participants with active SLE.

The Secondary Objectives of this Clinical Trial are:
- to evaluate the long-term effect of litifilimab on disease activity in participants with SLE
- to evaluate the long-term effect of litifilimab in participants with SLE in maintaining low disease activity
- to evaluate the effect of litifilimab in participants with active SLE in preventing irreversible organ damage
- to assess long-term use of OCS6 with participants receiving litifilimab treatment
- to assess the impact of litifilimab on participant-reported HRQoL, symptoms and impacts of SLE
- to evaluate long-term effect of litifilimab on laboratory parameters
- to evaluate immunogenicity of litifilimab

Study design

This is a multicenter, randomized, parallel-group, dose-blind, Phase 3 LTE study. This study will be conducted in participants who completed the 52-week duration of Study 230LE303 or Study 230LE304 on study treatment. Participants who were treated with BIIB059 in the parent Phase 3 studies will continue to receive BIIB059 treatments SC Q4W through the duration of this LTE study, in addition to at least 1 of the following nonbiologic lupus SOC therapies: antimalarials, OCS, or immunosuppressants.

Intervention

In this LTE study, participants who received randomized low dose BIIB059 and high dose BIIB059 SC Q4W during the parent Phase 3 studies will continue their respective doses. There will be no placebo arm as a comparator in this LTE. Participants who had received placebo during the parent Phase 3 studies will be randomized 1:1 in this LTE study to receive low dose BIIB059 or high dose BIIB059 SC Q4W with an additional corresponding dose at Week 2, as an add-on to background nonbiologic lupus SOC therapy. Participants will remain on their assigned dose of BIIB059 throughout the LTE study.

Study burden and risks

The treatment period will last for 152 weeks. Participants will have to visit the study center every month (every 4 weeks) up to Week 24, as well as at Week 2, Week 36, and Week 52. After Week 52, participants will have to visit the study center every 12 to 16 weeks up to Week 156. There will be at least 18 study visits. During these visits, participants will complete the study assessments and receive the study drug. In addition, participants will have to visit the study site every 4 weeks between these 18 visits, to receive study treatment but participants will not have study assessments with these visits.

Once the participant finish the study treatment period, the participant will enter the follow-up period after your End-of-Treatment visit. This is to check how the participant is doing after completing the study treatment period. The follow-up period lasts for 24 weeks. The participant will visit the study center 4 times and be contacted by the study team via telephone twice during this time.

Subjects will be expected to take the IP as instructed and patients be subjected to: questions regarding medical history, use of concomitant medications/procedures and adverse events; urine sampling; measurement of vital signs; measurement of weight/height; physical examination; skin assessments; ECGs and patient reported outcomes questionnaires.
Subjects will be expected to not take part in other medical studies, keep their appointments for visits, follow instructions from the study team, keep a patient card with them at all times, not donate eggs, to use appropriate forms of contraception and not discuss information about the study in public places while the study is in progress. Subjects will also be asked to complete a diary daily with questions about your their SLE and corticosteroid treatments.

Side effects that have been seen in >= 5% of the people treated with the study drug in 3 clinical studies aredescribed below:
• upper respiratory tract infection
• headache
• diarrhea
• common cold
• urinary tract infection
• fall
• redness at the injection site
• joint pain

Side effects may be mild or very serious/ life-threatening. Serious side effects that have been observed in patientstreated with the study drug in one of the previous clinical studies are hypersensitivity (allergic reaction), meningitis,pneumonia (a type of lung infection) and epilepsy (seizure).

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meningitis, pneumonia (a type of lunginfection) and epilepsy (seizure).
SLE is an autoimmune disease that affects multiple organ systems and has a significant adverse effect on patients* HRQoL. Currently, most therapies used to treat SLE are only partially effective and have considerable toxicity. Therefore, there is an unmet need for the development of additional efficacious therapies for SLE. The Phase 1 and Phase 2 efficacy data from completed BIIB059 clinical studies indicate that BIIB059 has the potential to decrease active lupus disease (e.g., lupus skin lesions and/or joint manifestations) and control disease activity in SLE, supporting the beneficial effect of BIIB059 in patients with SLE.

The data that are available to date from completed studies have shown that BIIB059 had an acceptable safety profile and was well tolerated.

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

1. Participants who completed 1 of the 52-week of the double-blind placebo-controlled,
parent Phase 3 studies (230LE303 and 230LE304) on study treatments with either BIIB059 or placebo to Week 48 and attended the last study assessment visit at Week 52.
2. Ability of the participant to understand the purpose and risks of the study, to provide informed consent, and to authorize the use of confidential health information in accordance with national and local privacy regulations.
3. All women of childbearing potential must agree to practice highly effective contraception during
the study and for 126 days (18 weeks) after their last dose of study treatment. In addition,
participants should not donate eggs during the study and for at least 126 days (18 weeks)
after their last dose of study treatment. Where applicable, if not previously confirmed in
the parent Phase 3 study, postmenopausal status must be confirmed as follows: for
women <= 55 years of age, 52 continuous weeks of natural (spontaneous) amenorrhea without an alternative medical cause and a serum FSH level >= 40 mIU/mL; for women
> 55 years of age, 52 continuous weeks of natural (spontaneous) amenorrhea without an
alternative medical cause and a serum FSH level >= 40 mIU/mL, or at least 5 continuous
years of natural (spontaneous) amenorrhea without an alternative medical cause.

Exclusion criteria

1. Early parent Phase 3 studies treatment terminators (participants who discontinued study treatment before Week 52).
2. Early parent Phase 3 studies terminators (participants who withdrew from study participation and did not complete the 52-week treatment period).
3. Participants who have developed any other medical diseases, conditions, or abnormalities, rendering their participation in the LTE study unsuitable in the opinion of the Investigator.
4. Participants who developed moderate-to-severe worsening of organ specific lupus manifestations that would require a change in immunosuppressive therapy.
5. Use of prohibited concurrent medication or therapy during the parent Phase 3 studies.
6. Immunization with live or live-attenuated vaccines within 4 weeks prior to

Baseline Visit.
7. Use of other investigational drugs or off-label drugs used to treat SLE, cutaneous lupus, or lupus nephritis during the parent Phase 3 studies.
8. Female participants who are pregnant, currently breastfeeding, or planning to become pregnant during the study and for 126 days (18 weeks) after the last dose of study treatment.
9. Current enrollment or a plan to enroll in any interventional clinical study in which an investigational treatment or approved therapy for investigational use is administered (participation in observational registries is allowed).
10. Inability to comply with study requirements.
11. Other unspecified reasons that, in the opinion of the Investigator or Sponsor, make the participant unsuitable for enrollment.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2023
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	N/A
Generic name:	BIIB059

Ethics review

Approved WMO Date:	05-10-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-01-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-04-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-10-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-04-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-04-2024
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
EU-CTR	CTIS2023-505635-13-00
EudraCT	EUCTR2021-006378-22-NL
ClinicalTrials.gov	NCT05352919
CCMO	NL82387.056.22