A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase 2 Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Rozanolixizumab in Adult Study Participants With Leucine-Rich Glioma Inactivated 1 Autoimmune Encephalitis

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• To assess the efficacy of rozanolixizumab as measured by seizure freedom• To assess the efficacy of ozanolixizumab as measured by change in cognitive function• To assess the efficacy of ozanolixizumab as measured by use of rescue medication• To...

Ethical review	Approved WMO
Status	Completed
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON54436

Source
ToetsingOnline

Brief title
AIE001

Condition

- Autoimmune disorders

Synonym
autoimmune encephalitis, leucine-rich glioma inactivated 1 autoimmune encephalitis (LGI1

AIE)

Research involving
Human

Sponsors and support

Primary sponsor: UCB Pharma
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: AIE001, autoimmune encephalitis, rozanolixizumab

Outcome measures

Primary outcome

• To assess the efficacy of rozanolixizumab as measured by seizure freedom:

Seizure freedom (defined by 28 consecutive days of

no seizures) maintained until the end of the Treatment Period (Week 25)

Secondary outcome

• To assess the efficacy of rozanolixizumab as measured by a change in

cognitive function: Change from Baseline in Repeatable Battery for the

Assessment of Neuropsychological Status (RBANS) total scale index score at the

end of the Treatment Period (Week 25)

• To assess the efficacy of rozanolixizumab as measured by use of rescue

medication: Use of rescue medication due to an absence or loss

of clinical benefit during the Treatment Period

• To assess the efficacy of rozanolixizumab as measured by the onset of seizure

freedom: Time to first occurrence of seizure freedom

(TTFSF) defined by the number of days after randomization to the first day of

the first 28

consecutive days without seizures during the Treatment Period

• To assess the safety and tolerability of rozanolixizumab: Incidence of

treatment-emergent

Study description

Background summary

Rationale: Autoimmune encephalitis (AIE) is a group of disorders where the immune system
causes inflammation of the brain, leading to debilitating neurological and psychiatric symptoms.
There are currently no approved treatments for AIE. Leucine-rich glioma inactivated 1 AIE
(LGI1 AIE) has a distinct clinical presentation and has been identified as a variant that may be
suitable for immunotherapy, and therefore for treatment with rozanolixizumab, which blocks the
activity of neonatal Fc receptor (FcRn), accelerates the catabolism of antibodies and reduces the
concentration of immunoglobulin (Ig) G.
To date, rozanolixizumab has been administered to human study participants in 4 completed
clinical studies (UP0018, UP0060, MG0002, and TP0001) and 6 ongoing studies (CIDP01,
CIDP04, MG0003, MG0004, TP0003, and TP0006).
Overall, repeated administrations of rozanolixizumab at a dose of approximating 7mg/kg sc were
generally well tolerated, with an acceptable safety profile in the completed studies. The TEAE
profile was similar between rozanolixizumab and placebo, except for headaches where increased
frequency and severity was observed in the rozanolixizumab-treated study participants. The peak
and total exposure of rozanolixizumab showed nonlinear increases consistent with targetmediated
drug disposition. Dose-dependent, statistically significant reductions in levels of total
IgG and dose-dependent reductions in levels of IgG subclasses (IgG 1 to 4) were observed after
rozanolixizumab was administered by intravenous (iv) or sc routes. In study participants with

generalized MG (gMG), clinically relevant improvements in day-to-day functioning were
observed following treatment with rozanolixizumab 7mg/kg compared with placebo.

Study objective

• To assess the efficacy of rozanolixizumab as measured by seizure freedom
• To assess the efficacy of ozanolixizumab as measured by change in cognitive function
• To assess the efficacy of ozanolixizumab as measured by use of rescue medication
• To assess the efficacy of rozanolixizumab as measured by the onset of seizure freedom
• To assess the safety and tolerability of rozanolixizumab

Study design

This is a Phase 2, multicenter, randomized, double-blind, placebo-controlled, 2-arm, repeat dose
study to evaluate the efficacy, safety, and PK of rozanolixizumab for the treatment of LGI1 AIE.
Approximately 68 adult study participants with LGI1 AIE with onset of disease between 0 to
12 months prior to study entry will be randomized to receive rozanolixizumab 560mg or placebo,
administered by subcutaneous (sc) infusion at weekly intervals for 24 weeks. A Treatment Period
of 24 weeks has been selected to ensure a sufficient time period to evaluate a difference between
rozanolixizumab and placebo in key symptoms of the disease. The primary objective of the study
is to assess the efficacy of rozanolixizumab as measured by seizure freedom.
Following screening and completion of the Baseline assessments, treatment will be initiated in
study participants who are currently considered for treatment with intravenous methylprednisolone (IVMP) by the investigator, or who have initiated IVMP treatment within
14 days prior to randomization at a dose of 500 to 1000mg/day. Down titration of steroids will
begin at the end of the 3 to 5-day (based on the decision of the investigator) IVMP regimen. If
the study participant has initiated a steroid taper, the study participant cannot receive oral
steroids at a dose lower than 60mg/day when randomized. Each subsequent down-titration step
will last for 7 days (±2 days; see Section 1.2).

The study participants will be stratified at randomization by:
• Time from disease onset (<=6 months or >6 months from disease onset)
• Cognitive function (RBANS score of <=85 or >85)
After the initial 5 investigational medicinal product (IMP) administrations have been performed
at the clinic, the study participant may have the opportunity to be treated at home by a visiting
healthcare practitioner.
Although the use of rescue medication is allowable at any time during the study, the use of
rescue medications should be delayed, if clinically appropriate, for at least 4 weeks following the
initiation of study treatment. Study participants who require rescue medication will discontinue
blinded treatment and complete the assessments for the Early Discontinuation Visit. Following
this, the selection of an appropriate rescue medication will be made at the investigators

discretion, and the study participant will enter the Safety Follow-Up (SFU) Period. Unscheduled
study visits are permitted for any study participant including those study participants who have
initiated rescue medication.
An Independent Data Monitoring Committee (IDMC) will be established for the study to
monitor the emerging safety data within the clinical study on a periodic basis.

Intervention

Treatment Groups and Duration
The maximum study duration per study participant is 34 weeks. There are 3 study periods:
• Screening Period: Eligibility will be assessed during the Screening Period of up to 14 days. If
a study participant becomes seizure free during the Screening Period as a result of IVMP
treatment, the participant may be randomized in the study, providing the prior occurrence of
seizures is well documented. Intravenous methylprednisolone can be initiated prior to the
start of the Screening Period, however, the study participant must be randomized within
14 days.
• Treatment Period: Participants who have been confirmed eligible will be

randomized in a
1:1 ratio to receive rozanolixizumab 560mg or placebo at weekly intervals over a 24-week
Treatment Period.
• Safety Follow-Up Period: Study participants who complete the 24-week Treatment Period or
prematurely discontinue IMP, as well as study participants who receive rescue medication
during the 24-week Treatment Period will undergo the End of Treatment (EOT) Visit/Early
Discontinuation Visit and enter the SFU Period. At 4 weeks after the final dose, study
participants will undergo a SFU phone call, and at 8 weeks after the final dose, study
participants will undergo the End of Study (EOS) Visit.

Study burden and risks

The therapy to be investigated may cause side effects or adverse effects. Your doctor will provide appropriate treatment and may perform further tests due to side effects but will explain this to you if necessary.
Possible side effects which you might experience when you receive the study drug, along with how often they are expected to occur are listed below.
• Very Common (occurring in 10% or more of the study participants):
- Headache
- Diarrhea
- Fever

• Common (occurring in 1% to less than 10% of the study participants):
- Vomiting
- Nausea
- Infusion/injection site reactions
- Upper respiratory tract infections (such as sore throat, sinus infection, common cold, cough)
- Oral herpes
- Joint and muscle ache
- Rash

Infusion re action including hypersensitivity (allergic reaction):
The study drug is a protein substance foreign to your body and like other proteins of this class (called monoclonal antibodies), it can cause infusion reactions. Some study participants reported a mild local reaction at the site where the drug was infused under the skin; in some study participants, it was accompanied by mild vomiting, mild fever, and/or mild to moderate diarrhea. Symptoms of hypersensitivity are itching, flushing (redness), hives, swelling of lips, tongue, eyes or face, headache, feeling dizzy, sweating, feeling sick

(nausea) or being sick (vomiting), feeling out of breath, and heart racing. You must inform your study doctor or study staff IMMEDIATELY if you have any or some of these symptoms particularly during the infusion or for the first few hours following the infusion. Your study doctor and/or site staff will provide treatment for this side effect if necessary.

There is a small risk that the result of the test for LGI1 does not provide accurate results. However, this risk would not be different than if you were tested for LGI1 outside of the study.
Possible side effects based on currently available information are described below. This information is based on limited study participant numbers at this stage of the drug development.
Headache:
In previous studies, when the study drug was administered as an infusion under the skin, some study participants reported headache. In most of the cases, the headache starts within 1 to 3 days following the study treatment and they are generally mild to moderate. In few cases, severe headaches were reported. The majority of these cases resolved spontaneously. In some cases, treatment with analgesic may be required to reduce the pain. To date, there have been no observations of any permanent ill effects associated with this side effect. If you suffer from this side effect, you must immediately inform your study doctor. Your study doctor will provide appropriate treatment or perform further tests for these side effects if necessary.
Gastrointestinal Upset:
In the same studies mentioned above, when the study drug was administered as an infusion under the skin, some study participants reported nausea (feeling sick or as you are going to throw up), vomiting (actually being sick or throwing up), and diarrhea. All these cases were mild to moderate, except a few cases of diarrhea that were severe in intensity. All resolved without any permanent ill effects on their health. Please let your doctor know if you have had recent history of inflammatory or ulcerative stomach or intestine diseases. If you suffer from these or other tummy symptoms, you must immediately inform your study doctor. Your study doctor will provide appropriate treatment or perform further tests if necessary.
Increased risk of infections:
Fever, sore throat, influenza and common cold, and cough have been reported in study participants receiving the study drug. However, in the previous studies, study participants who received rozanolixizumab were not found to be at a particularly increased risk of infections compared to study participants who received dummy drug (placebo). There was no the study drug -related evidence of infection in animals given this drug. However, the study drug works by reducing the level of antibodies (substances in your body that help fight off certain infections) in your body which may put you at increased risk of infections. You must let your study doctor or study staff know immediately if you have any symptoms of infections such as but not limited to feeling cold or shivery; your skin feels hot to touch; stinging or pain when you pass urine, or coughing etc.

Your study doctor will provide appropriate treatment or perform further tests if necessary.
In some study participants, the study drug may reduce the level of antibodies too much. In case this happens, your study medication may be temporarily stopped to decrease the risk of infections. Treatment with study medication will be restarted once the antibody levels have increased sufficiently.
Effects on your response to vaccines:
The study drug has potential to decrease the immunity against certain diseases for which you have received vaccines in the past. It can also modify the necessary response of your body to vaccines that you receive while the study drug is effective; for example, you may not develop protection against a disease from the vaccination; or taking a live vaccine may cause you to develop the illness it was supposed to prevent. You will not be eligible for participating in this study if you have received a live vaccine within 8 weeks before the Baseline Visit or you intend to have a live vaccination during the course of the study or within 8 weeks following the final dose of study medication. You must tell your study doctor if you have received or plan to receive any vaccination during this period. Vaccination with non-live vaccines (including COVID-19 vaccines) is permitted.
Effects on kidneys:
The study drug may have an effect on the kidney based on its mechanism of action. Results from previous clinical studies did not indicate any ill effects of the study drug on the kidney. However, your blood and urine samples will be taken regularly to ensure that your kidneys are in good health. Your study doctor will monitor you and provide appropriate treatment in case you experience this side effect. In addition, your doctor may need to change the dosage of your medications to take into account the health of your kidney at the time you enter the study.
Immunogenicity:
It is possible that your body develops a natural defense (antibodies) against the study drug (anti-rozanolixizumab-antibody). Positive anti-rozanolixizumab-antibody has been detected in animal studies, including in one animal who developed immune complex formation and an accelerated clearance of the study drug as the consequence of positive anti-drug antibody. The anti-rozanolixizumab-antibody can also result in side effects such as allergic reaction. However, the incidence and/or magnitude of the anti-rozanolixizumab-antibody response in animals does not predict such effects in humans. Positive anti-rozanolixizumab-antibody has also been detected in some patients treated with the study drug. It is not yet known if there are long-term effects associated with developing these antibodies. Blood samples will be collected to detect their presence. Your study doctor will monitor any potential side effects that may be associated with anti-rozanolixizumab-antibody.
Effects on albumin:
Albumin is a substance (protein) that performs many necessary functions in your body such as to prevent fluids from leaking out of your body vessels, carrying vital nutrients and hormones, and providing your body with substances it needs

for maintenance, repair and growth of your body. Hypothetically, the study drug may decrease the amount of albumin in your body. Mild and short-lived decreases in albumin were observed in some animals after administration of the study drug. However, the previous clinical studies did not indi

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

Protocol Amd 3 14Jan2022 section 5.1 Inclusion Criteria

-Study participant must be >=18 to <=89 years of age, at the time of signing the informed consent
-Study participant must be seropositive for leucine-rich glioma inactivated 1 (LGI1) antibody measured by LGI1 serum autoantibody cell-binding assay

-Study participant must have >=2 seizures/week during the Screening Period or have experienced such seizures that stopped following high dose corticosteroids (500 to 1000mg MP equivalent/day):

• Either FBDS with or without other focal (partial) seizures including focal to bilateral tonic clonic
• Or focal (partial) seizures including focal to bilateral tonic clonic and fulfil the following new-onset AIE criteria:
a. Subacute onset (rapid progression of less than 3 months) of working memory deficits (short-term memory loss), altered mental status (defined as decreased or altered level of consciousness, lethargy, or personality change), or psychiatric symptoms.
AND
b. At least one of the following:
i. New focal CNS finding, as per the investigator's assessment
ii. Seizures not explained by a previously known seizure disorder
iii. CSF pleocytosis (white blood cell count of >5 cells/mm3)
iv. MRI features suggestive of encephalitis (Brain MRI hyperintense signal on T2- weighted fluid-attenuated inversion recovery sequences highly restricted to one or both medial temporal lobes [limbic encephalitis], or in multifocal areas involving grey matter, white matter, or both compatible with demyelination or inflammation).
AND
c. Reasonable exclusion of alternative causes

-Study participant has initiated or re-initiated corticosteroids at a dose of 500 to 1000 mg MP equivalent/day within 42 days prior to randomization. Participants re-initiating corticosteroids are eligible only if re-initiation is due to seizure rebound and within the timeframe outlined in Section 4.1.
If the study participant has initiated a steroid taper, the study participant cannot receive an
oral steroid dose lower than 40 mg/day when randomized
-Study participant with onset of disease symptom between 0 to 12 months prior to Screening, per investigator's assessment.
-Study participant weighs at least 35 kg (for males and females) at Screening
*A male participant must agree to use contraception during the treatment period and for at least 90 days after the final dose of study treatment and refrain from donating sperm during this period
*A female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least one of the following conditions applies:
i) Not a woman of childbearing potential (WOCBP)
OR
ii) A WOCBP who agrees to follow the contraceptive guidance during the treatment period and for at least 90 days after the final dose of study treatment
8a. Study participant is capable of giving signed informed consent or has a legal representative to consent for him/her as described in Appendix 1 (Section

10.1.3) which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.
9a. Study participant has a reliable caregiver who will be available during the whole study period, as determined by the investigator.

Exclusion criteria

Protocol Amd 5 09Feb2023 section 5.2 Exclusion Criteria

Medical conditions
1. Study participant has any medical or psychiatric condition that, in the opinion of the investigator, could jeopardize or would compromise the study participant*s ability to participate in this study.
2. Study participant has a history of alcohol use disorder or other substance use disorder (as per Diagnostic and Statistical Manual of Mental Disorders-5) within the previous 12 months.
3. Study participant has a known hypersensitivity to any components of the study medication or any other anti-FcRn medications. This includes a known history of hyperprolinemia, since L proline is a constituent of the rozanolixizumab formulation.
4a. Study participant has a confirmed prior diagnosis of epilepsy or new onset seizures that are unrelated to LGI1 AIE or has any known or suspected medical cause for the onset of seizures other than possible AIE.
5. Study participant has a known active neoplastic disease or history of neoplastic disease within 5 years of study entry (except for basal or squamous cell carcinoma of the skin or carcinoma in situ of the uterine cervix which has been definitively treated with standard of care approaches).
6. Study participant has 12-lead ECG with findings considered clinically significant by the investigator.
7a. Study participant has renal impairment, defined as glomerular filtration rate (GFR) <30mL/min/1.73m2 at the Screening Visit.
8a. Study participant has a clinically important active infection (including unresolved or not adequately treated infection) as assessed by investigator, including participants with a serious infection within 6 weeks prior to the first dose of IMP.
9a. Study participant has a history of chronic ongoing infections (eg, Hepatitis B or C, human immune deficiency virus [HIV], active tuberculosis [TB]) or who tests positive for HIV, Hepatitis B or C at the Screening Visit.
* Presence of Hepatitis B surface antigen at the Screening Visit.
* Positive Hepatitis C antibody test result at Screening or within 3 months prior to the IMP dose. NOTE: Study participant with a positive Hepatitis C antibody due to prior resolved disease can be enrolled only if a confirmatory negative Hepatitis C RNA test is obtained.
10. Study participant has current unstable liver or biliary disease, per investigator assessment, defined by the presence of ascites, encephalopathy,

coagulopathy, hypoalbuminemia, esophageal or gastric varices, persistent jaundice, or cirrhosis. Note: An exception is stable chronic hepatobiliary conditions (including Gilbert*s syndrome, asymptomatic gallstones).
11. Study participant has positive TB test at the Screening Visit unless it is determined by a TB specialist that the positive result is related to an adequately treated latent TB infection
12. Study participants met any of the following TB exclusion criteria:
* Known active TB disease
* History of active TB involving any organ system unless adequately treated according to World Health Organization (WHO)/US Center for Disease Control therapeutic guidance and proven to be fully recovered upon consult with a TB specialist
* Latent tuberculosis infection (LTBI) (unless appropriate prophylaxis is initiated at least 4 weeks prior to IMP dosing and will be continued to completion of prophylaxis). Prophylaxis should be in accordance with applicable clinical guidelines and TB specialist judgment based on the origin of infection.
* High risk of exposure to TB infection, as assessed by the investigator
* Current nontuberculous mycobacterial (NTM) infection or history of NTM infection unless proven to be fully recovered.
For further information relating to definitions of known active TB, past history of TB, LTBI, high risk of acquiring TB infection see Section 10.12.
13. Study participant has a lifetime history of suicide attempt (including an active attempt, interrupted attempt, or aborted attempt), or had suicidal ideation with at least some intent to act in the past 6 months as indicated by a positive response (Yes) to either Question 4 or Question 5 of the Columbia Suicide Severity Rating Scale (C-SSRS) at Visit 1.
14. Removed in Protocol Amendment 4.
15. Study participant has a current or medical history of IgA deficiency.
16. Study participant has a history of solid organ transplant or hematopoietic stem cell transplant.
17. Study participant has undergone a splenectomy.
18. Study participant has a current or medical history of primary immune deficiency.
Prior/concomitant therapy
19. Study participant has been treated with prohibited immunosuppressants, biologics, and other therapies within the timeframe specified in Section 6.5.2.
20a. Study participant has received a live vaccination within 4 weeks prior to the Baseline Visit; or intends to have a live vaccination during the course of the study or within 8 weeks following the final dose of IMP.
Prior/concurrent clinical study experience
21. Study participant has been previously randomized in this study (rescreening for screen-failed participants is allowed with prior consultation and permission of the medical monitor/study physician).
22. Study participant has previously received rozanolixizumab drug product.
23. Study participant has participated in another study of an IMP (and/or an investigational device) within the previous 3 months or 5 half-lives prior to Baseline (whichever is longer) or is currently participating in another study

of an IMP (and/or an investigational device).
Diagnostic assessments
24b Alanine transaminase (ALT), aspartate aminotransferase (AST), or alkaline phosphatase (ALP) are >3x upper limit of normal (ULN).
* If study participant has >ULN for ALT, AST, or ALP that does not meet the exclusion limit at Screening, the tests must be repeated prior to dosing to ensure there was no further ongoing clinically relevant increase. In case of a clinically relevant increase as per the investigator's judgement, the study participant must be excluded.
* Tests that result in ALT, AST, or ALP up to 25% above the exclusion limit (>2xULN) may be repeated once for confirmation. This includes rescreening. If any of the repeated tests (ALT, AST, or ALP) are >2xULN, the study participant will meet the exclusion criterion #24 and the study participant must be excluded.
* For randomized study participants with a Baseline result >ULN for ALT, AST, ALP, or total bilirubin but <1.5xULN, a Baseline diagnosis and/or the cause of any clinically meaningful elevation will have to be understood and recorded in the electronic case report form (eCRF).
25. Bilirubin >1.5xULN (isolated bilirubin >1.5xULN is acceptable if bilirubin is fractionated and direct bilirubin <35%).
26. Removed in Protocol Amendment 5 as already incorporated in exclusion criterion #10.
27. Removed in Protocol Amendment 2, and incorporated in exclusion criterion #24.
28. Removed in Protocol Amendment 2, and incorporated in exclusion criterion #24.
29. Removed in Protocol Amendment 2, and incorporated in exclusion criterion #24.
30a. Study participant has a total IgG level <=5.5g/L at the Screening Visit.
31. Study participant has absolute neutrophil count <1500 cells/mm3 at the Screening Visit.
32. Study participant has a planned major elective surgical procedure for the duration of their participation in the study.
33. Removed in Protocol Amendment 4.

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:	Completed
Start date (anticipated):	21-04-2023
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	rozanolixizumab
Generic name:	rozanolixizumab

Ethics review

Approved WMO Date:	30-03-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-06-2021
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-09-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-09-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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Review commission:	METC Brabant (Tilburg)
Approved WMO	

Date:	02-05-2023
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Review commission:	METC Brabant (Tilburg)
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Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-01-2024
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	EUCTR2019-004778-25-NL
Other	IND: 146922
CCMO	NL75512.028.21