An Open-Label Extension Study to Investigate the Long-Term Safety, Tolerability, and Efficacy of Rozanolixizumab in Subjects With Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)

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CIDP04 is a Phase 2A, multicenter, single-arm, open-label study with the primary objective of evaluating the long-term safety and tolerability of rozanolixizumab when administered as weekly subcutaneous (sc) infusion in subjects with CIDP. The...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Demyelinating disorders
Study type	Interventional

Summary

ID

NL-OMON49386

Source
ToetsingOnline

Brief title
CIDP04

Condition

- Demyelinating disorders

Synonym
Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP)

Research involving

Human

Sponsors and support

Primary sponsor: UCB Biopharma SPRL
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: CIDP, Efficiacy, Open Label Extension, Rozanolixizumab, safety, tolerability

Outcome measures

Primary outcome

The primary objective of the study is to assess long-term safety and

tolerability of weekly doses of rozanolixizumab in subjects with CIDP.

Secondary outcome

The secondary objective of the study is to assess long-term clinical efficacy

of weekly doses of rozanolixizumab.

The exploratory objectives of the study are to assess the PD, PK, and

immunological variables in the treatment course with rozanolixizumab and to

assess whether long-term dosing of rozanolixizumab improves PROs.

Study description

Background summary

Production of pathogenic auto-antibodies is a major feature of a number of autoimmune diseases
often associated with a specific pathomechanism. Cellular and humoral immune mechanisms are
thought to be involved in the pathogenesis of CIDP resulting in inflammatory lesions in the
spinal roots, proximal nerve trunks, and along the peripheral nerves. The

essential role of the
autoimmune antibodies in mediating this pathology is supported by the improvement seen after
PLEX and IA. Identification of the specific antigenic target(s) of the autoimmune antibodies in
CIDP is expanding with recent immunological techniques. Treatments aimed at reducing the
quantity of circulating IgG auto-antibodies are being used for primary and secondary therapy of
autoimmune diseases, particularly where corticosteroid-based immune suppression is not or no
longer effective. The therapeutic approach of these treatments is based on lowering levels of
pathogenic auto-antibodies, which represents rational and effective treatment modalities of
autoimmune diseases.
Rozanolixizumab is a humanized IgG4 monoclonal antibody that is being developed as an
inhibitor of the activity of FcRn. The FcRn recycles IgG and albumin and transports it
bidirectionally across epithelial barriers. Recent studies have shown that FcRn rescues both IgG
and albumin from intracellular lysosomal degradation by recycling it from the sorting endosome
to the cell surface (Anderson et al, 2006). Rozanolixizumab has been specifically designed to
block IgG binding to FcRn without blocking the binding and recycling of albumin. By blocking
the activity of FcRn, rozanolixizumab accelerates the catabolism of IgG antibodies, including
IgG auto-antibodies. The aim is to reduce the concentration of pathogenic IgG in patients with
autoimmune diseases mediated by the action of IgG auto-antibodies.

Study objective

CIDP04 is a Phase 2A, multicenter, single-arm, open-label study with the primary objective of evaluating the long-term safety and tolerability of rozanolixizumab when administered as weekly subcutaneous (sc) infusion in subjects with CIDP. The secondary objective includes evaluating the long-term clinical efficacy of weekly doses of rozanolixizumab in the subjects with CIDP. This open-label study will provide subjects who participated in previous rozanolixizumab studies (eg, CIDP01) the opportunity to have continued access to rozanolixizumab.

Study design

The CIDP04 study includes a 24-week Treatment Period followed by an 8 week Observation Period. For the 24-week Treatment Period, subjects will have weekly visits (either on site or at home) during which they will be dosed with an sc infusion of rozanolixizumab, up to 10mg/kg.

Intervention

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Study burden and risks

The study load includes:
Visits: 29 visites
Blood collection: 16 keer
Urine collection: 16 keer
IMPD infusion (SC): 24 keer

ECG: 16 keer
Physical examinationk: 13 keer
Questionnaires about the ability to perform daily and social activities, and about signs and symptoms of tuberculosis.

The subject may experience physical or psychological discomfort with the aforementioned tests, prodcedures and questionnaires. The subject may get side effects from the study medication.

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

- Subject has completed one of the previous rozanolixizumab study(ies) that allow access to the present study (e.g. study CIDP01)
- Female subjects of childbearing potential must agree to use a highly effective method of birth control, during the study and for a period of 2 months after their final dose of investigational medicinal product (IMP)
- Male subjects with a partner of childbearing potential must be willing to use a condom when sexually active during the study and for 3 months after the final administration of IMP

Exclusion criteria

- Subject has any medical (acute or chronic illness) or psychiatric condition that, in the opinion of the investigator, could harm the subject or would compromise the subject*s ability to participate in this study
- Subject has a clinically relevant active infection (eg, sepsis, pneumonia, abscess)
- Subject has a known hypersensitivity to any components of rozanolixizumab
- Subject intends to have a live vaccination during the course of the study or within 7 weeks following the final dose of rozanolixizumab
- Subject has an ongoing serious adverse event (SAE) or a medical condition in the parent study that the investigator considers to put the subject at a significantly increased risk of participating in CIDP04
- Subject has any planned elective surgery due to occur during the study dosing period which in the opinion of the investigator could interfere with study

procedures

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2020
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Rozanolixizumab
Generic name:	Rozanolixizumab

Ethics review

Approved WMO Date:	09-09-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2018-004392-12-NL
ClinicalTrials.gov	NCT04051944
CCMO	NL69688.018.19