A multi-center, uncontrolled extension study evaluating efficacy and safety of SAR153191 on top of DMARDs in patients with active Rheumatoid Arthritis (RA)

Published: 06-03-2014
Last updated: 20-04-2024

To document the long term safety and efficacy of sarilumab added to DMARDs.

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

Summary

ID

NL-OMON41668

Source
ToetsingOnline

Brief title
RA-EXTEND

Condition

- Joint disorders

Synonym
arthritis, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis
Source(s) of monetary or material Support: Sanofi-aventis

Intervention

Keyword: efficacy, rheumatoid arthritis, safety

Outcome measures

Primary outcome

Safety assessment of sarilumab over time.

Secondary outcome

Proportion of patients who achieve ACR20, DAS28 remission and EULAR response

over time;

HAQ-Di results over time;

Study description

Background summary

Rheumatoid arthritis (RA) is a chronic, debilitating disease that primarily affects the synovial membrane of diarthrodial joints.
This study is intended to provide a long term safety database to better identify potential late onset adverse events associated with the use of sarilumab given in addition to DMARDs, as well as to asess long term efficacy.

Study objective

To document the long term safety and efficacy of sarilumab added to DMARDs.

Study design

An uncontrolled open label extension study of sarilumab 200 mg q2w; added to DMARDs for a duration up to 5 years from the first administration, or until commercially available in each patient's country or until discontinuation of the project whichever sooner.

Intervention

A single subcutaneous injection of 200 mg sarilumab every two weeks on top of DMARDs.

Study burden and risks

The most common side effects reported in previous studies with sarilumab: Infections, laboratory abnormalities, reactions such as redness, itching, pain at the injection site, headaches, diarrhea, mouth ulcers, allergic reactions.

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

Patient with Rheumatoid Arthritis (RA) who was previously randomized in the sarilumab RA clinical program: e.g., the EFC11072 study, ACT11575 study, EFC10832 study, or SFY13370 study

Exclusion criteria

- Patient with any adverse event leading to permanent study drug discontinuation from a prior study.
- Treatment with any concurrent biologic agents including investigational drugs for the treatment of Rheumatoid Arthritis (RA)
- Patients with an abnormality(ies) or adverse event(s) that per investigator judgment would adversely affect participation of the patient in the study

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2014
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	not yet available
Generic name:	sarilumab

Ethics review

Approved WMO

Date:	06-03-2014

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	02-04-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	03-07-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	09-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	13-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	16-12-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	06-01-2016

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	03-05-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	11-05-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	06-06-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	08-06-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	21-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	27-11-2018

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	04-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2010-019262-86-NL
ClinicalTrials.gov	NCT01146652
CCMO	NL47910.048.14