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

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

Summary

ID

NL-OMON34585

Source
ToetsingOnline

Brief title
LTS11210 / Mobility_extension

Condition

- Autoimmune disorders

Synonym
arthritis, RA

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi-aventis

Source(s) of monetary or material Support: Sponsor

Intervention

Keyword: anti-Interleukin 6R monoclonal Antibody, rheumatoid arthritis

Outcome measures

Primary outcome

The primary objective of the study is to evaluate the long term safety of

SAR153191 in patients with RA on top of DMARDs.

Secondary outcome

The percentages of patients who reach ACR20, DAS28 and EULARresponse overtime.

Study description

Background summary

Rheumatoid arthritis (RA) is a chronic, debilitating disease that primarily affects the synovial membrane of diarthrodial joints. Currently, treatment of RA involves the use of nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids and disease modifying anti-rheumatic drugs (DMARDs). Methotrexate, sulfasalazine, hydroxychloroquine and leflunomide are DMARDs that have been used by rheumatologists for many years.
Introduction of biologic agents, especially inhibitors of TNF-α, has greatly improved the therapeutic options available for treating RA; however, no therapeutic modality provides either universal or complete control of disease and safety remains one of the key issues with anti-TNF-α treatment.
Besides early benefit/risk of biologics, the long term outcome of RA remain a critical question: long term use of biologics have been associated with immunosuppression and effects on the development of infections, malignancies, demyelinating events, lupus like events, etc*To deal with this concern, long-term data are needed to allow comparison with well established adverse events in this population.

Study objective

The primary objective of the study is to evaluate the long term safety of SAR153191 in patients with RA on top of DMARDs.
The secondary objective of the study is finding the percentages of patients who

reach ACR20, DAS28 and EULAR response overtime.

Study design

This is a multicenter, multinational open label long term study, only for patients with RA who participated in the study EFC11072 and completed Part A (12 weeks of treatment) or Part B (52 weeks of treatment) or patients who were randomized in Part B of the study EFC11072 in a
treatment arm subsequently not retained following pivotal dose selection.
Patients need to sign a specific informed consent in order to participate in the LTS11210 study.
Initially patients will receive 150 mg of SAR153191 SC weekly for up to 260 weeks of treatment (from the first intake of SAR153191 in the study EFC11072) or until commercially available, whichever comes first. During screening at V1 (D-7 to D-1) patients will have a safety evaluation
and will be assessed for concomitant medications and eligibility to the study.
The last treatment visit in the study EFC11072 will be used as the screening visit. In addition patients will have a CPK test (only at screening).
At Day 1 (week 0) after confirmation of eligibility, they will receive the administration of the first dose of SAR153191 150 mg SC at the investigational site and will be reminded on how to self inject.
They will be reminded to self inject 7 days apart. At dosing time points occurring outside site visits, SAR153191 can be injected by the patient himself, or by a trained caregiver.
Patients will return for follow up visits according to the flow chart for additional laboratory testing, questionnaires and joint examination.
Initially, patients will receive the highest dose tested in EFC11072 part A, currently 150 mg weekly. This dose will be switched to a lower dose regimen in case of discontinuation of this treatment arm, or selection of a lower pivotal dose regimen.
The Investigators will check all laboratory parameters during this study. In case of increased LFTs, or decreased neutrophil counts, a reduction of dose, initially 150 mg every other week will be permitted, as well as adjustment of DMARDs dosage.
Patients who discontinue treatment before the planned end of treatment should have a safety follow up visit, Visit 29, six weeks after the end of treatment.

Intervention

Open label long term study treatment: Max. 260 weeks, weekly injection with SAR153191.

Study burden and risks

Risks are related to blood sampling, X-ray and possible side effects of the (administration of) the study drug. The burden for the patient will be the

number of visits to the center as part of the trial. In addition, the patient is asked to fill in a diary.

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

- Patients with RA who were randomized in the study EFC11072 (a randomized, double-blind, placebo-controlled study in patients with active rheumatoid arthritis who are inadequate responders to MTX therapy)
• and who have completed Part A (12 weeks) or Part B (52 weeks) of the study EFC11072.
• or patients randomized in Part B of EFC11072 to a treatment arm subsequently not retained following pivotal dose selection.
- Patients must give informed consent for participating in the study LTS11210 prior to any procedure related to the study.

Exclusion criteria

- Patients not willing to continue to take folic acid 5 mg weekly or greater with the MTX dose, to minimize toxicity.
- Patients with any contraindications to MTX according to SmPC or investigators judgment.
- Any patient who experienced an adverse event leading to discontinuation from EFC11072.
- Any abnormalities or adverse events at screening (last treatment visit in the study EFC11072 will be the screening visit) that per investigator judgment would adversely affect patient*s participation in this study
- Subject with an active TB at the last treatment visit in the study EFC11072.
- Female of child bearing potential with a positive pregnancy test.
- For women of childbearing potential (WOCBP), unwillingness to utilize adequate contraception methods or not become pregnant during the full course of the study.
- Men who are unwilling to utilize 2 form of contraception: a condom and a spermicidal agent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	19
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	nog niet beschikbaar
Generic name:	SAR153191

Ethics review

Approved WMO Date:	05-07-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-02-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	22-04-2011
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL32893.058.10
Other	Zie gegevens onder sectie J.