An Observational, Prospective Cohort Study to Evaluate Safety and Efficacy of RemsimaTM in Patients with Rheumatoid Arthritis

First published: 11/02/2015

Last updated: 15/02/2019

Study Ongoing

Administrative details

EU PAS number

EUPAS8571

Study ID

28166

DARWIN EU® study

No

Study countries

Denmark

Korea, Republic of

Romania

Spain

Study description

The objective of this study is to assess the long-term safety and efficacy of RemsimaTM in Rheumatoid Arthritis (RA) patients.

Study status

Ongoing

Research institutions and networks

Institutions

Sf.Maria Clinical Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

KyungMin Baek postmarket_safetyreport@celltrion.com

Study contact

postmarket_safetyreport@celltrion.com

Primary lead investigator

SungHwan Park

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 11/12/2014

Study start date
Planned: 30/09/2015

Actual: 30/09/2015

Data analysis start date
Planned: 31/01/2016

Date of interim report, if expected
Planned: 31/05/2016

Date of final study report
Planned: 30/10/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Celltrion

Study protocol

CT-P13 4 2_RA registry protocol_EU-specific_Ver 2.1 03Jun15_Synopsis for PASS_clean.pdf (31.86 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness
Effectiveness study (incl. comparative)

Main study objective:

The primary objective of this study is to assess the long-term safety and efficacy of RemsimaTM in Rheumatoid Arthritis (RA) patients.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

REMSIMA

Medical condition to be studied

Disseminated tuberculosis

Cardiac failure congestive

Opportunistic infection

Serum sickness

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

450

Study design details

Outcomes

to assess the long term safety of Remsima in RA patients, to evaluate efficacy in patients with RA

Data analysis plan

the statistical analysis will be performed using SAS software version.9.1.3 or later. Interim report of study results will be generated every May from 2016 and the final report will be generated in 2026.

Documents

Study, other information

01 EULAR 2017_CT-P13 4.2 2Y_Abstract (publication only).pdf (185.04 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No