An Observational, Prospective Cohort Study to Evaluate Safety and Efficacy of RemsimaTM in Patients with Ankylosing Spondylitis(AS)

First published: 20/04/2015

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Study Ongoing

Administrative details

EU PAS number

EUPAS9491

Study ID

28172

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Czechia
- ☐ France

☐ Germany

☐ Korea, Republic of

Study description

The primary objective of this study is to assess the safety of RemsimaTM in ankylosingspondylitis (AS) patients, in comparison with patients receiving other anti-TNF drugs, by evaluation ofevents of special interest (ESI) for up to 5 years from the first visit of each patient.The secondary objectives of this study are to evaluate efficacy and additional safety of RemsimaTM in ASpatients, in comparison with patients receiving other TNF blockers. Health-economics parameters will alsobe assessed.

Study status

Ongoing

Research institutions and networks

Institutions

Revmatologicky ustav

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Institution

Contact details

Study institution contact

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Primary lead investigator

TaeHwan Kim

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 14/01/2015

Study start date
Actual: 26/05/2015

Data analysis start date
Planned: 21/01/2016

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

Date of final study report
Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Celltrion

Study protocol

CT-P13 4.4 AS Registry Protocol v2.1 (EU spec)_03Jun15_Synopsos for PASS_clean.pdf(28.19 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

Main study objective:

The primary objective of this study is to assess the safety of RemsimaTM in ankylosingspondylitis (AS) patients

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

REMSIMA

Medical condition to be studied

Ankylosing spondylitis

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

500

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.

Data management

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