An Observational, Prospective Cohort Study to Evaluate Safety of Remsima® Subcutaneous in Patients with Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis and Psoriasis (CT-P13 4.8)

First published: 20/12/2022

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS50207

Study ID

103361

DARWIN EU® study

No

Study countries

Belgium

Czechia

Finland
France
Germany
Italy
United Kingdom

Study description

This study is an observational, prospective cohort study to assess the safety of Remsima® Subcutaneous by evaluation of adverse events of special interest and to evaluate additional safety of Remsima® Subcutaneous in Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA) and Psoriasis (Ps) patients. Approximately 288 male or female patients with RA will be enrolled and treated with Remsima® SC and approximately 576 male or female patients (288 patients in each treatment group of Remsima® SC and IV) with AS, PsA and Ps will be enrolled and treated with either Remsima® SC or IV. This study will be carried out according to routine practice in European region.

Study status

Ongoing

Research institutions and networks

Institutions

Celltrion

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Jee Hye Suh jeehye.suh@celltrion.com

Study contact

jeehye.suh@celltrion.com

Primary lead investigator

Yun Ju Bae

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/10/2022

Study start date

Planned: 02/01/2023

Actual: 13/01/2023

Data analysis start date

Planned: 31/03/2027

Date of interim report, if expected

Planned: 30/09/2025

Date of final study report

Planned: 30/09/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Celltrion Inc.

Regulatory

Was the study required by a regulatory body?

No

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:

Safety study (incl. comparative)

Main study objective:

The main objective of this study is to evaluate safety of Remsima® subcutaneous in patients with Rheumatoid Arthritis, Ankylosing Spondylitis,

Psoriatic Arthritis and Psoriasis.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AB02) infliximab

infliximab

Medical condition to be studied

Rheumatoid arthritis

Ankylosing spondylitis

Psoriatic arthropathy

Psoriasis

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

864

Study design details

Outcomes

Primary objective of this study is to assess the safety of Remsima® Subcutaneous (SC) in Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA) and Psoriasis (Ps) patients by evaluation of adverse events of special interest (AESI). Secondary objective of this study is to evaluate additional safety of Remsima® SC in RA, AS, PsA and Ps patients.

Data analysis plan

Results will be summarized using descriptive statistics (n, mean, median, standard deviation SD, minimum, and maximum) for quantitative variables and frequencies for qualitative variables. Demographics (age, gender, weight, height, and race) will be summarized in tables in the safety population. Previous medical history will be presented by means of summary tables. In addition, for RA patients, the safety results will be systematically compared against the historical cohorts of patients from published peer-reviewed clinical studies and post-marketing studies conducted with infliximab (IV and SC formulation), including but not limited to Studies CT-P13 3.5, 1.6 and risk management plan. For AS, PsA, and Ps patients, the results of Remsima® SC will be compared against the patients in Remsima® IV group who receive at least 1 (full or partial) dose of Remsima® IV.

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, For RA patients, the safety results will be systematically compared against the historical cohorts of patients from published peer-reviewed clinical studies and post-marketing studies conducted with infliximab (IV and SC formulation), including but not limited to risk management plan.

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