An observational, prospective cohort study to evaluate the safety and efficacy of Remsima in patients with Crohn's disease (CD) and Ulcerative Colitis (UC)

First published: 10/06/2015

Last updated: 15/02/2019

Study Ongoing

Administrative details

EU PAS number

EUPAS9917

Study ID

28169

DARWIN EU® study

No

Study countries

- ☐ Czechia
- ☐ Italy
- ☐ Korea, Republic of

- [ ] Netherlands
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Sweden
- [ ] United Kingdom

Study description

The primary objective of this study is to assess the safety of Remsima™ by evaluation of Events of Special Interest (ESI) in IBD patients, who have active Crohn’s disease (CD), fistulizing Crohn’s disease (CD), or Ulcerative Colitis (UC) for up to 5 years for each patient.The secondary objectives of this study are to evaluate additional safety and efficacy of Remsima™ in IBD patients, who have active CD, fistulizing CD or UC. Health-economic parameters will also be assessed.

Study status

Ongoing

Research institutions and networks

Institutions

Fakultni nemocnice Ostrava Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jaehee Cheon

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/11/2014

Study start date

Planned: 16/12/2014

Actual: 16/12/2014

Data analysis start date

Planned: 31/01/2016

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 3 IBD registry protocol_EU-specific_Ver 2.1_Final_03Jun15 Synopsis for PASS_clean.pdf(31.03 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:

to assess the safety of Remsima™ by evaluation of Events of Special Interest (ESI) in IBD patients, who have active Crohn’s disease (CD), fistulizing Crohn’s disease (CD), or Ulcerative Colitis (UC) for up to 5 years for each patient.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

REMSIMA

Medical condition to be studied

Crohn's disease

Colitis ulcerative

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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 long term safey of Remsima in IBD patients, to evaluate efficacy in patients with IBD

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