Post-Marketing Surveillance of REMSIMA 100mg (Infliximab) (monoclonal antibody, gene recombination) to Evaluate Its Safety and Efficacy in Korea (REMSIMA_PMS)

First published: 09/09/2015

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10911

Study ID

28448

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

This surveillance is conducted for a period of four years from the approval date (July 20, 2012), at six-month intervals for the first two years and one-year intervals for the subsequent two years, as part of a marketing authorisation conditions in Republic of Korea, where the efficacy and safety of the approved medicinal product are closely monitored under the 're-examination period'.The objectives of this post-marketing surveillance (PMS) are to evaluate the safety and efficacy of REMSIMA in Korea under routine care and identify the issues regarding the following: (1) Serious adverse events (SAEs) and adverse drug reactions (ADRs). SAE or ADR is considered as such if it: (a) results in death or is life-threatening, (b) requires inpatient hospitalization or prolongation of existing hospitalization,(c) causes a persistent or significant disability/incapacity, (d) results in a congenital anomaly/birth defect, or (e) is associated with any other medically important condition. (2) Unexpected adverse events and adverse drug reactions that are not reflected in the directions for the use of drug(3) Already known adverse drug reactions(4) Non-serious adverse events (5) Other information about safety and efficacy

---

Study status

Finalised

Research institutions and networks

Institutions

Celltrion

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 39 centres are involved in the study

Contact details

Study institution contact

KyungMin Baek postmarket_safetyreport@celltrion.com

Study contact

postmarket_safetyreport@celltrion.com

Primary lead investigator

KyungMin Baek

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/07/2012

Study start date

Actual: 23/01/2013

Data analysis start date

Actual: 20/07/2012

Date of final study report
Actual: 19/07/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Celltrion Inc.

Study protocol

REMSIMA_PMS_v5.0_eng (2).pdf(790.86 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The objectives of this post-marketing surveillance (PMS) are to evaluate the safety and efficacy of REMSIMA in Korea under routine care and identify the issues regarding SAEs, ADRs, unexpected AEs and ADRs, already known ADRs, non-serious AEs and other information about safety and efficacy.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study

Study drug and medical condition

Name of medicine

REMSIMA

Medical condition to be studied

Rheumatoid arthritis

Crohn's disease

Psoriasis

Ankylosing spondylitis

Colitis ulcerative

Psoriatic arthropathy

Population studied

Short description of the study population

All intended patients from the first patient to receive REMSIMATM for any indication approved to the agreed number of cases were consecutively enrolled as patients in the post-marketing surveillance (PMS)

Age groups

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

1600

Study design details

Data analysis plan

<Method of safety analysis>Overall incidence rate of adverse events and its 95% confidence interval are made available, all serious or unexpected AEs and ADRs are analysed in terms of incidence and causality, incidence rate analysis based on background factors, concomitant medications and drug administration history and other relevant data, a logistic regression analysis, and, identification of causes for drug withdrawal. <Method of efficacy analysis>Efficacy of Remsima is analysed in terms of short-term effectiveness (or ineffectiveness) based on the criteria for evaluation of primary efficacy and according to background factors, concomitant medications and drug administration histories of subjects, logistic regression analysis to estimate factors that may affect analysed effective rates, and, McNemar test or Bowker test is performed on differences between long-term and short-term outcomes of Remsima in subjects for long-term surveillance.

Documents

Study results

REMSIMA-PMS_Re-examination report_final_1.pdf(7.53 MB)

Study report

REMSIMA-PMS_Re-examination report_final_2.pdf(7.17 MB)

REMSIMA-PMS_Re-examination report_final_3.pdf(7.59 MB)

REMSIMA-PMS_Re-examination report_final_4.pdf(7.35 MB)

Study, other information

REMSIMA-PMS_Re-examination report_final_3.pdf(7.59 MB)

REMSIMA-PMS_Re-examination report_final_4.pdf(7.35 MB)

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

The sponsor, when visiting the study center, will collect Clinical Research Forms (CRFs) completed during the run-in period. Any and all documents created during the re-examination period including records about post-marketing surveillance, source documents and CRFs shall be placed on file immediately when collected and kept in proper storage for three years after completion of the re-examination.

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

Unknown