Post-Marketing Surveillance of REGKIRONA ® 960mg (Regdanvimab)(monoclonal antibody, gene recombination) to Evaluate Its Safety and Efficacy (CT-P59 4.1)

First published: 12/04/2022

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Study Ongoing

Administrative details

EU PAS number

EUPAS46141

Study ID

46142

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

Post-Marketing Surveillance of REGKIRONA 960 mg (Regdanvimab) (monoclonal antibody, gene recombination) to Evaluate Its Safety and Efficacy. The regimen and dosage of Regdanvimab shall follow that of approved by Ministry of Food and Drug Safety in Korea. The objectives of this post-marketing surveilance (PMS) are to evaluate the safety and efficacy of regdanvimab in Korea under routine care.

Study status

Ongoing

Research institutions and networks

Institutions

Celltrion

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Institution

Contact details

Study institution contact

Jung Nahyun nahyun.jung@celltrion.com

Study contact

nahyun.jung@celltrion.com

Primary lead investigator

Ahn Keumyoung

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/03/2021

Study start date

Actual: 03/03/2021

Date of final study report

Planned: 08/02/2027

Sources of funding

- EU institutional research programme

More details on funding

Celltrion Inc.

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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

The objectives of this post-marketing surveillance (PMS) are to evaluate the safety and efficacy of Regdanvimab 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 drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J05AX) Other antivirals

Other antivirals

Medical condition to be studied

COVID-19

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

3000

Study design details

Outcomes

The objectives of this post-marketing surveillance (PMS) are to evaluate the safety and efficacy of Regdanvimab 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.

Data analysis plan

A table showing the list of advers events by type shall be created and the severity, causal relationships and outcome of adverse events shall be analyzed. Unexpected ADRs shall be presented in the summary table. The surveilance will analyse, as necessary, the incidence rate of AEs, depending on the subject's background factors. Analysis of the incidence rate according to the type of abnormal changes in the clinical laboratory test values and the incidence rate

of ADE will be performed. In order to examine factors that are thought to affect efficacy, the surveilance will analyse the rate of disease progression, depending on the subject's background factors.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Post-Marketing Surveillance

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