Post-Marketing Safety Study on Olumiant (Baricitinib) Use Among Moderate to Severe Active Rheumatoid Arthritis Patients in China

First published: 23/03/2020

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Study Finalised

Administrative details

EU PAS number

EUPAS34213

Study ID

34214

DARWIN EU® study

No

Study countries

☐ China

Study status

Finalised

Research institutions and networks

Institutions

Peking Union Medical College Hospital

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Institution

Multiple centres: 31 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Xiao feng Zeng

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/05/2020

Actual: 01/05/2020

Study start date
Planned: 31/08/2020

Actual: 31/08/2020

Data analysis start date
Actual: 25/11/2022

Date of final study report
Planned: 30/12/2022

Actual: 09/05/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli lilly

Study protocol

Non_interventional PASS Protocol_B021(a).pdf(400.3 KB)

Non_interventional PASS Protocol_B021_amendment (b).pdf.pdf(6.13 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of this study is to describe the incidence of AEs, SAEs over a period of 12 weeks. The secondary objectives are to describe the

incidence of AEs, SAEs over a period of 24 weeks, and to describe the effectiveness and patient-reported outcomes of Olumiant 2 mg in the study population.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Single-country, single arm, prospective study

Study drug and medical condition

Name of medicine

OLUMIANT

Population studied

Short description of the study population

The study population included patients aged 18 years or older moderate to severe active rheumatoid arthritis (RA) who had received treatment with Olumiant identified through the Chinese registry of rheumatoid arthritis (CREDIT).

Inclusion Criteria:

- Are at least 18 years old

 Diagnosed with moderate to severe active RA
 Prescribed with Olumiant according to the approved label by the investigator in the routine care of the patient
 Provide written consent to the release of their data after being informed of the study.

Exclusion Criteria:
 Are simultaneously participating in a different study that includes a treatment intervention and/or an investigational drug
 Contraindicated for the use of Olumiant according to the approved label

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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)

Special population of interest

Other

Special population of interest, other

Rheumatoid arthritis patients

Estimated number of subjects

667

Study design details

Outcomes

Safety outcomes, all AEs/SAEs will be collected and analyzed. Effectiveness outcomes: change from baseline to Weeks 12 and 24 in 28 diarthrodial joint count (DAS28)-C-reactive protein (CRP), in Simplified Disease Activity Index (SDAI) score and in Clinical Disease Activity Index (CDAI) score, mean duration of Morning Joint Stiffness (MJS) and mean Visual Analogue Scale (VAS) for pain in Weeks 12 and 24 as collected in e-diaries.

Data analysis plan

In general, descriptive summary statistics will include the followings: • For categorical variables: number, number missing, frequency, and percentage (with the percentage excluding the number missing in the denominator) • For continuous variables: number, number missing, mean, median, standard deviation, minimum, maximum All calculated values should be reported with at least 2 decimal places. If the calculated value is greater than or equal to 0.01, 2 decimal places will be retained. Otherwise, 3 decimal places will be retained. Two-sided significance level of 0.05 will be used. For p-values, 4 decimals will be retained. Subgroup analyses may be performed for AEs, SAEs and effectiveness. No adjustment for multiplicity will be performed. Analysis will be conducted using Statistical Application Software (SAS), Version 9.2 or higher.

Documents

Study results

I4V-GH-B021(b) Non-interventional PASS final study report (3).pdf(9.95 MB)

Data management

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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