

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

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS34213

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### Study ID

34214

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### DARWIN EU® study

No

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### Study countries

 China

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### 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

Yu Dong [dong\\_yu1@lilly.com](mailto:dong_yu1@lilly.com)

Study contact

[dong\\_yu1@lilly.com](mailto:dong_yu1@lilly.com)

### 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

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### **Study start date**

Planned: 31/08/2020

Actual: 31/08/2020

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### **Data analysis start date**

Actual: 25/11/2022

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### **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

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

Not applicable

**Methodological aspects**

**Study type**

**Study type list**

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

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**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

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### **Non-interventional study design, other**

Single-country, single arm, prospective study

## Study drug and medical condition

### **Medicinal product name**

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)
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**Special population of interest**

Other

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**Special population of interest, other**

Rheumatoid arthritis patients

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**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.

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## 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)

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## 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)

[Disease registry](#)

[Other](#)

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No