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

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# 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 by	study required by a requiate	ory body:	7
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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).

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☐ 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
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
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

# **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

### 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**

# **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

No