Rheumatologist and Dermatologist Survey to Assess the Effectiveness of the Risk Minimisation Measures (RMM) for Olumiant (baricitinib), a JAK1/2 inhibitor (I4V-MC-B025)

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Last updated: 21/05/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/43240

EU PAS number
EUPAS43239

Study ID
43240

DARWIN EU® study
No

Study countries
France
Germany
United Kingdom

Study description
This study will assess: a) effectiveness of the updated baricitinib healthcare professional (HCP) educational materials and Patient Alert Card among dermatologists and rheumatologists and b) the effectiveness of a Direct Healthcare Professional Communication (DHPC) distributed to dermatologists and rheumatologists. This study was updated as a result of the Article 20 referral for JAKi, the protocol was endorsed by PRAC.

Study status
Ongoing

Research institution and networks

Institutions

United BioSource Corporation (UBC)

Switzerland
First published: 25/04/2013
Last updated
06/03/2024

Institution

Non-Pharmaceutical company

ENCePP partner

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Kristin Meyers

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
15/09/2021

Study start date
Planned:
31/03/2024
Actual:
27/03/2024

Date of final study report

Planned:
30/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

LY3009104 B025(b) NI PASS Protocol_Redacted.pdf(493.76 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 type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Study design:
This study uses a multi-national, observational cross-sectional design.

Main study objective:
1) assess effectiveness of updated HCP Educational Materials and PAC among dermatologists and rheumatologists. Key risk messages within these materials include those pertaining to pregnancy, infections, lipids, VTE, MACE, malignancy and dosing. 2) The effectiveness of a DHPC distributed to dermatologists and rheumatologists.

Study Design

Non-interventional study design
Cross-sectional

Study drug and medical condition

Name of medicine
Olumiant

Study drug International non-proprietary name (INN) or common name
BARICITINIB

Anatomical Therapeutic Chemical (ATC) code
(L04AA37) baricitinib

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
400

Study design details

Outcomes
The proportion of HCPs who demonstrate understanding of the important safety information in HCP Educational Materials and in the DHPC. We will also report proportion who report communication of important safety information to their patients prescribed

baricitinib for the first time and the proportion who distribute the PAC to patients prescribed baricitinib for the first time.

Data analysis plan
Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for responses to questions that address the survey objectives (i.e. excluding demographic questions). Survey data will be analysed overall, and stratified by country, prescriber status (has previously prescribed baricitinib or has not previously prescribed baricitinib), and by number of patients treated.

Data management

Data sources

Data sources (types)
Other

Data sources (types), other
Data for this study will be collected through a survey of dermatologists.

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