An observational post-authorisation safety study (PASS) in Europe to further characterise and quantify long-term safety profile with respect to neurotoxicity, chronic nephrotoxicity, and malignancy with use of voclosporin

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000284

Study ID

1000000284

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Czechia
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This PASS will evaluate the long-term risks with use of voclosporin in lupus nephritis (LN) patients treated with voclosporin in the real-world setting in Europe, as per the approved Summary of Product Characteristics (SmPC), by assessing the incidence of the following safety events: neurotoxicity, chronic nephrotoxicity, and any malignancy.

Study status

Ongoing

Research institutions and networks

Institutions

Otsuka Pharmaceutical Netherlands B.V.

Contact details

Study institution contact

Barbara Eschenbach beschenbach@otsuka-europe.com

Study contact

beschenbach@otsuka-europe.com

Primary lead investigator

Peter Psarologos

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/07/2024

Study start date

Actual: 23/12/2024

Date of final study report

Planned: 31/12/2030

Study protocol

348-201-0021_Voclo-PA_Final_08Aug2023_approved.pdf (19.32 MB)

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)

Other study registration identification numbers and links

348-201-00021

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Primary Objective:
- To describe the incidence rate (IR) of neurotoxicity in LN patients who initiated voclosporin treatment
- To describe the IR of chronic nephrotoxicity in LN patients who initiated voclosporin treatment
- To describe the IR of any malignancies in LN patients who initiated voclosporin treatment

Secondary Objective:
To describe the incidence proportions of neurotoxicity, chronic nephrotoxicity, and any malignancies in LN patients who initiated voclosporin

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
LUPKYNIS

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

Anatomical Therapeutic Chemical (ATC) code
(L04AD03) voclosporin
voclosporin

Population studied

Age groups

Adult and elderly population (≥18 years)

Special population of interest

Other

Special population of interest, other

Lupus Nephritis

Estimated number of subjects

300

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.

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