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

- [ ] Czechia
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Spain
- [ ] Sweden
- [ ] 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

Planned: 21/05/2024

Actual: 18/07/2024

Study start date

Planned: 31/01/2025

Actual: 03/02/2025

Date of final study report

Planned: 31/12/2030

Sources of funding

- Pharmaceutical company and other private sector

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

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