

# 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

**First published:** 06/12/2024

**Last updated:** 02/09/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000284

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### Study ID

1000000284

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### DARWIN EU® study

No

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### Study countries

- ☐ Austria
  - ☐ Belgium
  - ☐ Czechia
  - ☐ Italy
  - ☐ Netherlands
  - ☐ Poland
  - ☐ Spain
  - ☐ Sweden
  - ☐ Switzerland
  - ☐ United Kingdom
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### **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.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

[Otsuka Pharmaceutical Netherlands B.V.](#)

## Contact details

### Study institution contact

Barbara Eschenbach [beschenbach@otsuka-europe.com](mailto:beschenbach@otsuka-europe.com)

Study contact

[beschenbach@otsuka-europe.com](mailto:beschenbach@otsuka-europe.com)

### Primary lead investigator

Peter Psarologos

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 18/07/2024

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### Study start date

Actual: 23/12/2024

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### 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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

### **Medicinal product name**

LUPKYNIS

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

VOCLOSPORIN

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### **Anatomical Therapeutic Chemical (ATC) code**

(L04AD03) voclosporin

voclosporin

## Population studied

## Age groups

- **Adult and elderly population ( $\geq 18$  years)**

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## Special population of interest

Other

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## Special population of interest, other

Lupus Nephritis

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## 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

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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