

# A Post-Authorisation Disease Registry Safety Study to Generate Data on the Long-Term Safety and Clinical Effectiveness of SCENESSE® (Afamelanotide 16mg) in Patients with Erythropoietic Protoporphyrria (EPP). (SCENESSE® PASS-002)

**First published:** 01/04/2016

**Last updated:** 13/02/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS13004

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### Study ID

46827

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### DARWIN EU® study

No

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### Study countries

## Study description

This non-interventional study has been designed to gather long-term safety data and outcome endpoints. The objectives are to assess whether SCENESSE® can be used safely within designated treatment centres and to generate data to support the clinical effectiveness derived from the use of SCENESSE®

Note: Protocol version for countries where patients treated off-label cannot be included in the disease registry

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## Study status

Ongoing

## Research institutions and networks

### Institutions

#### Porphyria Center Düsseldorf

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

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**Study contact**

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**Primary lead investigator**

Emilie Rodenburger

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 30/06/2016

Actual: 26/09/2016

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**Study start date**

Planned: 31/07/2016

Actual: 14/11/2016

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**Date of final study report**

Planned: 01/06/2027

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Clinuvel

## 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 2 (specific obligation of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

#### **Main study objective:**

The study has been designed to assess whether SCENESSE® can be used safely within porphyria treatment centres and to generate data on long term safety and outcome endpoints derived from the use of SCENESSE®. The

recommended risk minimization measures and the effectiveness of the controlled distribution of SCENESSE® will also be assessed.

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Non-Interventional Study

## Study drug and medical condition

### **Medicinal product name**

SCENESSE

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

AFAMELANOTIDE

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

(D02BB02) afamelanotide

afamelanotide

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### **Medical condition to be studied**

Porphyria non-acute

## Population studied

## **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
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## **Estimated number of subjects**

200

# Study design details

## **Outcomes**

Gather long-term safety data on SCENESSE®, Evaluate compliance with the risk minimization measures

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## **Data analysis plan**

Safety assessment as outlined above will occur via the European EPP Disease Registry. Treatment-emergent adverse events and the use of concomitant medications will be assessed at every visit to the treatment centre and recorded using electronic CRFs. Compliance with the risk minimization measures will be assessed against the designated criteria throughout the study while the effectiveness of the controlled distribution of SCENESSE® will be evaluated every 12 months. Analysis of Clinical Effectiveness All patients enrolled in the registry will be included in the assessment of clinical effectiveness so long as data are available. In general, baseline will be the data recorded on entry into the Registry. In general, clinical effectiveness will also be summarised by the subgroup variables, SCENESSE exposure at entry and Season of enrolment.

## 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](#)

## 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