

# A regulatory requirement non-interventional study to monitor the safety and effectiveness of Spesolimab in Korean patients with flares with generalized pustular psoriasis

**First published:** 24/07/2024

**Last updated:** 08/04/2026

Study

Discontinued

## Administrative details

### EU PAS number

EUPAS1000000278

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### Study ID

1000000278

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### DARWIN EU® study

No

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### Study countries

Korea, Republic of

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### Study status

Discontinued

## Contact details

### Study institution contact

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Study contact

[hyelin.lee.ext@boehringer-ingenelheim.com](mailto:hyelin.lee.ext@boehringer-ingenelheim.com)

### Primary lead investigator

Hyelin Lee

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 09/08/2023

Actual: 09/08/2023

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### Study start date

Planned: 30/03/2026

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### Date of final study report

Planned: 31/05/2029

## Study protocol

[1368-0122-protocol\\_Redacted.pdf](#) (1.29 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)?

Non-EU RMP only

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Study design:**

This is a single-arm, open-label, multi-center, observational and non-interventional study based on newly collected data.

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

The primary objective is to monitor the safety profile of Spesolimab IV in Korean patients

with flares with GPP in routine medical practice.

The secondary objective is to monitor the effectiveness of Spesolimab IV by evaluating changes in the GPPGA pustulation sub-score (mandatory), GPPGA score (mandatory), GPPASI (if collected), pain VAS (if collected) and PSS (if collected) from baseline after 1 week and/or 4 weeks.

## Study Design

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

Cohort

## Study drug and medical condition

### **Medicinal product name**

SPEVIGO

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

SPESOLIMAB

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

(L04AC22) spesolimab

spesolimab

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

Pustular psoriasis

## Population studied

## Age groups

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

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- Elderly ( $\geq 65$  years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

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## Special population of interest

Other

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### Special population of interest, other

Korean patients with flares with generalized pustular psoriasis

## 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