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

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Study Discontinued

Administrative details

EU PAS number

EUPAS1000000278

Study ID

1000000278

DARWIN EU® study

No

Study countries

Korea, Republic of

Study status

Discontinued

Contact details

Study institution contact

Hyelin Lee hyelin.lee.ext@boehringer-ingelheim.com

Study contact

hyelin.lee.ext@boehringer-ingelheim.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

Study start date

Planned: 30/03/2026

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

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

Study type:

Non-interventional study

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

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

SPESOLIMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC22) spesolimab

spesolimab

Medical condition to be studied

Pustular psoriasis

Population studied

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Special population of interest

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No