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: 24/07/2024

Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000278

EU PAS number
EUPAS1000000278

Study ID
1000000278

DARWIN EU® study
No

Study countries
Korea, Republic of

Study status
Planned

Contact details

Study institution contact

Hyelin Lee
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

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

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine
Spevigo

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

Anatomical Therapeutic Chemical (ATC) code
(L04AC22) 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

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