Post-marketing Surveillance of Spesolimab I.V. Infusion in improvement of Generalized Pustular Psoriasis (GPP) with acute symptoms in Japan (PMS for GPP with acute symptoms)

First published: 25/11/2022

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Study Finalised

Administrative details

EU PAS number

EUPAS49953

Study ID

49954

DARWIN EU® study

No

Study countries

Japan

Study description

The primary outcome is the incidence of investigator/BI-defined drug reactions (including safety concerns: Serious infections, Serious hypersensitivity).

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Yukako Ogi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/09/2022

Study start date

Actual: 01/03/2023

Date of final study report

Actual: 04/09/2026

Sources of funding

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

Study protocol

1368-0093_Protocol_and_Protocol_Amendment_23_Sep_2026__Public (1).pdf (1.48 MB)

1368-0093_Protocol_and_Protocol_Amendment_23_Sep_2026__Public.pdf (1.48 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

Other study registration identification numbers and links

1368-0093, NCT05670821

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Non-interventional cohort study

Main study objective:

The primary outcome is the incidence of investigator/BI-defined drug reactions (including safety concerns: Serious infections, Serious hypersensitivity).

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

Additional medical condition(s)

acute symptoms of generalized pustular psoriasis

Population studied

Short description of the study population

Inclusion criteria-GPP patients with acute symptoms who are administered Spesolimab I.V. Infusionin Japan

Patients who have never been treated with Spesolimab before enrolment

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

40

Study design details

Setting

Sites (mainly hospitals) at which Spesolimab I.V. Infusion are available for prescription throughout entire country

Outcomes

The incidence of adverse drug reactions (ADRs)

Data analysis plan

analyses are descriptive in nature, including confidence intervals.

Summary results

In this PMS, a total of 52 patients were registered. CRFs were collected and fixed for all 52 patients. All 52 patients were included in the safety set. Of these, 51 patients were included in the effectiveness set. One patient was excluded from the effectiveness set because of “No effectiveness outcomes”.
Primary outcome
ADRs were reported in 7 of 52 patients (13.46%). ADRs were observed in 3 of 52 patients (5.77%) at <7 days and in 4 of 52 patients (7.69%) at 7 to <28 days after administration of spesolimab, whereas no ADRs were observed at ≥28 days. No ADRs were observed in the 2 patients who received the re-administration of spesolimab. No statistically significant factors associated with the occurrence of ADRs were identified in the logistic regression analysis of subgroups.

Documents

Study results

1368-0093_Synopsis_redacted.pdf (256.68 KB)

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)

Other

Data sources (types), other

Prospective patient-based data collection

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