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

Last updated: 02/09/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49954

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

Planned

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Yukako Ogi

Study contact

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Primary lead investigator

Yukako Ogi

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 22/09/2022

Actual: 22/09/2022

Study start date
Planned: 01/03/2023

Date of final study report
Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

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

Name of medicine

SPEVIGO

Medical condition to be studied

Pustular psoriasis

Additional medical condition(s)

acute symptoms of generalized pustular psoriasis

Population studied

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

Outcomes

The incidence of adverse drug reactions (ADRs)

Data analysis plan

analyses are descriptive in nature, including confidence intervals.

Data management

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