A Non-Interventional Multi-Country Post-Authorisation Safety Study (PASS) to Assess the Incidence of Serious Infections & Malignancies in Systemic Lupus Erythematosus (SLE) Patients Exposed to Anifrolumab (SIMA PASS)

First published: 03/07/2023

Last updated: 02/07/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/106836

EU PAS number

EUPAS105690

Study ID

106836

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ France
- ☐ Germany
- ☐ Spain

Study description

This is an observational study, in which the main research question is to evaluate the risk of malignancies and serious infections among moderate/severe SLE patients who receive anifrolumab compared with a comparable population of moderate/severe SLE patients on standard of care (SOC) who do not initiate anifrolumab.

Study status

Planned

Research institutions and networks

Institutions

IQVIA

☐ United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution **Non-Pharmaceutical company** **ENCePP partner**

Contact details

Study institution contact

Mickael Arnaud

Study contact

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Primary lead investigator

Mickael Arnaud

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/03/2022

Actual: 29/03/2022

Study start date

Planned: 31/05/2025

Data analysis start date

Planned: 01/08/2025

Date of interim report, if expected

Planned: 31/05/2027

Date of final study report

Planned: 30/11/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

AZ Saphnelo PASS study protocol v3.0_Redacted.pdf(6.52 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Primary objectives are to estimate the incidence and compare hazard rates of new malignancies and the first occurrence of a serious infection (as a composite outcome) in moderate/severe SLE patients initiating anifrolumab and in comparable moderate/severe SLE patients who do not initiate anifrolumab (exposed to SLE SOC).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ANIFROLUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AA51) anifrolumab

anifrolumab

Medical condition to be studied

Systemic lupus erythematosus

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

4941

Study design details

Outcomes

Malignancies will be defined as the first coded diagnosis for haematological malignancies and solid tumours available in the data sources. Serious infection will be defined as an infection leading to hospitalisation, use of intravenous antimicrobials or an infection-related death. Specific types of malignancies: haematologic, solid and skin malignancies. Serious infection components: infection leading to hospitalisation, infection requiring treatment with IV antimicrobials and infection-related death. Serious infection types grouped as opportunistic serious infections, other serious infections, pneumonia (overall), fatal and non-fatal pneumonia (separately).

Data analysis plan

A full description of the analytical approach will be developed and described in the SAP. Details on data derivations, category definitions, analyses, handling of missing data, and presentation of the study results will be provided in SAP. SAP will be finalised prior to the conduct of the study analyses. All study results will be presented separately for each country in the study reports, as appropriate

when data become available. The final study report will include all descriptive, comparative, exploratory and sensitivity analyses as well as the meta-analysis for all the data sources.

Data management

Data sources

Data source(s)

Danish registries (access/analysis)

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

SNDS France, SHI Germany

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Hospital medication registries

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