Long-term, observational cohort study of adults with plaque psoriasis (PsO), who are new users of deucravacitinib, tumour necrosis factor inhibitor (TNFi) biologics, non-TNFi biologics, or non-biologic therapies in the real-world clinical setting

First published: 01/08/2025

Last updated: 09/01/2026

Study | Planned

Administrative details

EU PAS number

EUPAS1000000659

Study ID

1000000659

DARWIN EU® study

No

Study countries

Denmark
Finland
France
Germany
Norway
Spain

Study status

Planned

Research institutions and networks

Institutions

University of Southern Denmark (SDU)

Denmark

First published: 01/02/2024

Last updated: 27/03/2024

Institution | Educational Institution

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/12/2025

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

The Norwegian Institute of Public Health

Norway

First published: 01/02/2024

Last updated: 22/07/2024

Institution | Hospital/Clinic/Other health care facility | Other

University Medical Centre Hamburg-Eppendorf

Germany

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Spanish Academy of Dermatology and Venereology (AEDV)

University of Eastern Finland (UEF)

Networks

The SIGMA Consortium (SIGMA)

- Denmark
- European Union
- France
- Germany
- Italy
- Netherlands
- Norway
- Spain
- Sweden
- United Kingdom

First published: 10/02/2013

Last updated: 19/01/2026

Network | ENCePP partner

Contact details

Study institution contact

Transparency and Disclosure Lead ctt.group@bms.com

Study contact

ctt.group@bms.com

Primary lead investigator

Julie Scotto

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 06/01/2025

Study start date
Planned: 15/12/2025

Date of final study report
Planned: 24/12/2032

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

Study protocol

IM011-194_Redacted Protocol_04Nov2025.pdf (17.37 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Study design:

This is an observational cohort study using longitudinal real-world data from 6 databases and/or established disease registries in Europe. PsO treatment episodes for each patient will be classified into 4 cohorts: deucravacitinib, non-TNFi biologics, TNFi biologics, and non-biologic therapies.

Main study objective:

The primary objective of this study is to estimate the incidence rates of serious/select infections, malignancies, and select cardiovascular (CV) events among adult patients with PsO who are new users of deucravacitinib or treatments in 1 of the 3 comparator cohorts (CV events of interest are MACE, eMACE, and VTE) and to compare the risk of serious/select infections, malignancies, and select CV events (MACE, eMACE, and VTE) between deucravacitinib and each of the 3 comparator cohorts.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SOTYKTU

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

DEUCRAVACITINIB

Anatomical Therapeutic Chemical (ATC) code

(L04AF07) deucravacitinib

deucravacitinib

Medical condition to be studied

Psoriasis

Additional medical condition(s)

Plaque Psoriasis

Population studied

Short description of the study population

The study will include adult patients in Europe with diagnosed Plaque Psoriasis (PsO) who are new users of deucravacitinib or treatments from 1 of the 3 comparator cohorts during the indexing period.

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)

Estimated number of subjects

12800

Study design details

Comparators

The composition of the non-biologic therapy cohort will vary according to the assessed outcome

to consider the differential risks associated with these comparators:

- For serious/select infections, the non-biologic therapy cohort will encompass apremilast and acitretin.
- For malignancies, the non-biologic therapy cohort will encompass apremilast and acitretin.
- For MACE and eMACE from select CV events, the non-biologic therapy cohort will encompass apremilast, methotrexate, and dimethylfumarate.
- For VTE from select CV events, the non-biologic therapy cohort will encompass apremilast, methotrexate, cyclosporin, dimethyl fumarate, and acitretin.

Outcomes

The outcomes measured for this study include serious/select infections, malignancies, select CV events (MACE, eMACE, and VTE), and fatal events of the safety outcomes.

Data analysis plan

Descriptive statistics for baseline demographic data, clinical characteristics, and duration of exposure will be presented by treatment cohort.

Incidence rates and 95% confidence intervals (CIs) will be calculated for each outcome of interest over the entire observation period and at 1 year, 3 years, and 5 years of follow-up. Incidence rates will be reported overall for each treatment cohort and stratified by whether or not patients were PsO treatment-experienced (ie, received a systemic therapy from 1 of the other treatment cohorts prior to their episode index date except for deucravacitinib).

For each outcome of interest, weighted Cox proportional hazards regression models will be developed to estimate adjusted (ie, marginal) hazard ratios (HR) and 95% CIs for deucravacitinib versus each of the 3 comparator cohorts (pairwise comparisons). Inverse probability of treatment weighting (IPTW) based

on propensity score (PS) will be used to account for observed differences in characteristics across the treatment cohorts.
Patients can contribute multiple treatment episodes to each analysis, so the resulting correlated variance will be reflected in the final analysis using a robust variance estimator. Additionally, several sensitivity analyses will be conducted to assess the robustness of the results.

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 source(s)

Système National des Données de Santé (French national health system main database)

Data source(s), other

The Danish Registries

The Norwegian National Registries

The Finnish National Registries

The German Registry on the Treatment of Psoriasis with Biologics and Systemics (PsoBest)

The Spanish Registry of Systemic Treatments in Psoriasis (BIOBADADERM)

Data sources (types)

Disease registry

Other

Data sources (types), other

National Health Registry/Data System

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Unknown

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after extract-transform-load to a common data model