COHORT STUDY ON THE SAFETY OF BIMEKIZUMAB IN PATIENTS WITH PLAQUE PSORIASIS, PSORIATIC ARTHRITIS, AXIAL SPONDYLOARTHRITIS, OR HIDRADENITIS SUPPURATIVA: A NON-INTERVENTIONAL POST AUTHORIZATION STUDY

First published: 12/03/2025

Last updated: 29/04/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000003

Study ID

1000000003

DARWIN EU® study

No

Study countries

France

United States

Study status

Ongoing

Contact details

Study institution contact

UCB Cares UCBCares@ucb.com

Study contact

UCBCares@ucb.com

Primary lead investigator

Sebastian Schneeweiss

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/12/2022

Actual: 19/12/2022

Study start date

Planned: 10/03/2025

Actual: 13/03/2025

Date of final study report

Planned: 31/12/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB Biopharma SRL

Study protocol

ps0038-pass-protocol-v3-public.pdf (2.23 MB)

ps0038-pass-protocol-amend-3-17Oct2024_Public (1).pdf (2.98 MB)

ps0038-pass-protocol-amend-1-public.pdf (3.05 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)

Other study registration identification numbers and links

PS0038

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)

Data collection methods:

Secondary use of data

Study design:

The study is a sequential new-user active-comparator cohort design using secondary healthcare data.

Main study objective:

The primary purpose of this post-authorization safety study (PASS) within an active surveillance system will be to provide timely information on any potential increase in the risk of outcomes of interest in PSO, PsA, and axSpA patients using bimekizumab compared to other biologics indicated for moderate to severe plaque PSO, PsA, or axSpA, except for other anti-IL-17 biologics.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

bimekizumab

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

BIMEKIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC21) bimekizumab

bimekizumab

Medical condition to be studied

Psoriasis

Axial spondyloarthritis

Hidradenitis

Psoriatic arthropathy

Study design details

Setting

This non-interventional study will analyze secondary data from the US and EU healthcare system (Huybrechts and Schneeweiss, 2021). It is anticipated that all study patients in the EU and US databases will be identified in the respective databases starting Q1 2023 for the [REDACTED] and potentially Q3 2023 for the commercial US claims databases.

Outcomes

Outcomes of interest will include, but are not limited to, the following: MACE, malignancy, IBD, serious infection, and serious hypersensitivity. If additional outcomes of interest are identified, they will be considered for inclusion in the analysis to the extent that the data sources used in this study will contain

sufficiently detailed information.

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.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes