Post Authorization Safety Study (PASS) to Investigate Relevant Safety Outcomes among Patients Treated with Benepali for Psoriasis within the British Association of Dermatologists Biologic Interventions Register (BADBIR)

First published: 17/08/2026

Last updated: 24/09/2026

Study | Finalised

Administrative details

EU PAS number

EUPAS1000001086

Study ID

1000001086

DARWIN EU® study

No

Study countries

Ireland

United Kingdom

Study description

To assess the long-term safety and the risk of serious adverse events in psoriasis patients treated with Benepali (etanercept) compared to conventional systemic therapies with comparable disease severity, using data from the BADBIR registry.

Study status

Finalised

Research institutions and networks

Institutions

University of Manchester

United Kingdom

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Last updated: 01/02/2024

Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Eunjin Jo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/05/2016

Actual: 01/05/2016

Study start date

Planned: 01/05/2016

Actual: 01/05/2016

Date of final study report

Planned: 21/07/2026

Actual: 21/07/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Samsung Bioepis NL B.V.

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

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:

This is a prospective, non-interventional observational cohort study utilizing data from the BADBIR registry. It compares the long-term safety of Benepali (etanercept) to conventional systemic therapies in patients with psoriasis

across the UK and Republic of Ireland.

Main study objective:

The main objective of this study is to assess the long-term safety and the risk of serious adverse events in psoriasis patients treated with Benepali (etanercept) compared to those receiving conventional systemic therapies with comparable disease severity. Specifically, the study aims to evaluate the incidence rates of serious infections, malignancies, demyelinating diseases, tuberculosis, and other safety events of interest. This assessment is conducted by utilizing real-world data prospectively collected within the British Association of Dermatologists Biologic Interventions Register (BADBIR).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

BENEPALI

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

ETANERCEPT

Anatomical Therapeutic Chemical (ATC) code

(L04AB01) etanercept

etanercept

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

Psoriasis patients treated with Benepali (etanercept)

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

451

Study design details

Setting

Patients were recruited from 85 dermatology centres across the UK and ROI. Data were collected via online Case Report Forms every six months for the first 3 years and annually thereafter. The data were linked to national healthcare providers (e.g., NHS Digital) to capture additional information on mortality,

malignancy, and overnight hospital admissions.

Comparators

Those receiving conventional systemic therapies with comparable disease severity

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Outcomes

The following pre-selected events, which were agreed at a European Meeting (Manchester 2002) involving three rheumatology Biologics Registers (UK, Sweden and Germany) alongside the pharmaceutical companies that market biologic therapy and form the basis for the “Manchester Template”, and death were analyzed:

• Aplastic anaemia, pancytopaenia, serious neutropenia
• Cerebrovascular accident (CVA)
• Hepatitis B reactivation
• Lymphoproliferative disease
• Malignancy (not including skin)
• Melanoma or skin cancer including Bowen’s disease
• Myocardial infarction / acute coronary disease
• Pregnancy
• Pulmonary embolism
• Serious demyelination / optic neuritis
• Serious congestive heart failure
• Serious hepatic dysfunction/failure
• Serious hypersensitivity reaction
• Serious infection (excluding tuberculosis)
• Serious lupus / lupus-like illness
• Serious psoriasis flare
• Serious skin reaction (e.g. Stevens Johnson syndrome, erythema multiforme

toxic epidermal necrolysis)

• Surgery (overnight hospitalisation)

• Tuberculosis (not latent)

Summary results

Benepali was well-tolerated with no new safety signals identified. Total Serious Infection incidence was 26.3/1,000 person-years in the Benepali group versus 34.4/1,000 person-years in the conventional group (adjusted HR 0.74, 95% CI: 0.50-1.09). Skin (non-cancer) events were significantly lower in the Benepali group (adjusted HR 0.15). No tuberculosis or haematologic events were reported in the Benepali cohort. The benefit-risk profile remains positive.

Documents

Study report

SB4_BADBIR_Final Study Report_Final.pdf (710.32 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 source(s), other

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