SABLE: A 5-Year Prospective Observational Registry to Assess Adverse Events of Interest and Effectiveness in Adults with Active, Autoantibody-Positive Systemic Lupus Erythematosus Treated With or Without Benlysta (Belimumab) (116543)

First published: 16/10/2013

Last updated: 09/03/2026

Study Finalised

Administrative details

EU PAS number

EUPAS4966

Study ID

45713

DARWIN EU® study

No

Study countries

- Argentina
- Austria
- Belgium
- Canada
- France
- Germany
- Israel
- Italy
- Portugal
- Slovakia
- Spain
- Sweden
- United States

Study status

Finalised

Research institutions and networks

Institutions

Quintiles

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Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

Study contact

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Primary lead investigator

GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/10/2012

Actual: 31/10/2012

Study start date

Planned: 21/02/2013

Actual: 21/02/2013

Date of final study report

Planned: 08/09/2025

Actual: 05/09/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

BEL116543 (hgs1006-c1124-01).pdf (358.26 KB)

gsk-116543-protocol-amend4-redact.pdf (987.99 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This was a multi-center, prospective, observational cohort study.

Main study objective:

Evaluate the incidence of following AESI over 5 years in adults with active auto antibody positive SLE treated with/without BENLYSTA: Malignancies, Mortality, Opportunistic infections & other infections of interest, Non-melanoma skin cancer, Selected serious psychiatric event, Serious infections.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Multi-center, prospective, observational cohort study

Study drug and medical condition

Medicinal product name

BENLYSTA

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

BELIMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG04) belimumab

belimumab

Medical condition to be studied

Systemic lupus erythematosus

Population studied

Short description of the study population

Adults with active autoantibody-positive systemic lupus erythematosus (SLE) who are treated with or without Benlysta.

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

3.000

Study design details

Setting

The first participant was enrolled in the study on 21 February 2013 and the last participant last visit was on 28 February 2025. Participants were enrolled at sites in Argentina, Austria, Belgium, Canada, France, Germany, Israel, Italy, Portugal, Slovakia, Spain, Sweden, and the US.

Comparators

Not receiving Benlysta (comparison Non-Benlysta exposure group)

Outcomes

Incidence of the following adverse events of special interest (AESI):
- Malignancies (excluding non-melanoma skin cancers)
- Mortality
- Opportunistic infections and other infections of interest (Appendix 1)
- Non-melanoma skin cancers (NMSC)
- Selected serious psychiatric events (Appendix 2)
- Serious infections

Evaluate the effectiveness measures in adults with active autoantibody-positive SLE treated with/without BENLYSTA:
- Organ damage assessed by SLICC/ACR Damage Index
- Concomitant SLE meds including steroids
- Hospitalization
- Quality of life assessed by SF-12v2 Health Survey
- Fatigue assessed by FACIT-Fatigue Scale
- SLE disease activity assessed by SLEDAI 2000
- Severe Flare derived by SLE Flare Index

Data analysis plan

Estimate AESI via incidence rates & compared between cohorts using binomial regression and/or Cox models / Kaplan-Meier plots based on one or more exposure strategies as described:
(1, 2) patients contribute data until their first treatment switch, or a pre-specified landmark timepoint,
(3) Ever-taken Benlysta strategy, an event will be attributed to BENLYSTA if the patient was ever exposed to BENLYSTA prior to the event, & to non-Benlysta otherwise,
(4) patient profile approach, patients are characterized by the switch patterns,
(5) the as-exposed analysis or marginal structural methods may be used to model treatment switch and explore the long-term treatment effect. Safety analysis may employ a lagged risk window since an AE may be attributed to a treatment after discontinuation. Similar methods will be applied to the effectiveness endpoints. Propensity score methods and/or multivariate regression methods will be used to adjust for potential confounding factors & selection bias.

Documents

Study report

Clinical Study Report Body Consolidated Anonymised 19 Feb 2026.pdf (8.08 MB)

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 data source

Data source(s), other

Prospective patient-based data collection

Data sources (types)

Electronic healthcare records (EHR)

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