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: 10/02/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45713

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

Ongoing

Research institutions and networks

Institutions

Quintiles

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

GSK Clinical Disclosure Advisor

Study contact

Pharma.CDR@gsk.com

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: 18/07/2025

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

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

Other

Non-interventional study design, other

Multi-center, prospectiv, observational cohort study

Study drug and medical condition

Name of medicine

BENLYSTA

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

BELIMUMAB

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

3000

Study design details

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.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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