A Nationwide Post-Marketing Study on the Safety of Abatacept Treatment in Sweden Using the SRQ Register

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Study Finalised

Administrative details

EU PAS number

EUPAS31529

Study ID

32093

DARWIN EU® study

No

Study countries

Sweden

Study description

An expansion of ongoing post-marketing monitoring of abatacept to include all patients with rheumatoid arthritis (RA) and psoriatic arthritis (PsA) treated with abatacept with a specific look at select malignancies outcomes.

Study status

Finalised

Research institutions and networks

Institutions

Karolinska Institutet

Sweden

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Institution | Educational Institution

Contact details

Study institution contact

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Study contact

Alyssa.dominique@bms.com

Primary lead investigator

Alyssa Dominique

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 21/06/2019

Study start date
Planned: 01/10/2019

Actual: 01/10/2019

Date of final study report
Planned: 31/05/2025

Actual: 22/08/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb

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)

Other study registration identification numbers and links

BMS IM101-816

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Safety study (incl. comparative)

Main study objective:

The objective of this study is to estimate the incidence of pre-specified events of malignancies in abatacept-exposed patients and patients receiving select comparators enrolled in the ARTIS Register.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ORENCIA

Medical condition to be studied

Rheumatoid arthritis

Psoriatic arthropathy

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

4.000

Study design details

Data analysis plan

Incidence of pre-specified malignancies will exclude events reported in the first 180 days of follow-up. Overall cancer IR (95% CI) per 100 p-y and the IR rate will be calculated for abatacept users, anti-TNF users, non-anti-TNF users, and for biologic naive patients. Adjusted HRs will be calculated. Each cohort will be analyzed overall and stratified by indication.

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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

The Swedish prescribed drug register

Data sources (types)

Disease registry

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