A Nationwide Post-Marketing Study on the Safety of Abatacept Treatment in Denmark Using the DANBIO Register

First published: 25/09/2019

Last updated: 20/03/2026

Study Finalised

Administrative details

EU PAS number

EUPAS31532

Study ID

32096

DARWIN EU® study

No

Study countries

Denmark

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

Aalborg University Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Clinical for Internal and Emerg Medicine,The North Denmark Region

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Alyssa Dominique

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 13/06/2019

Study start date

Planned: 01/10/2019

Actual: 01/10/2019

Date of final study report

Planned: 01/05/2025

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 IM101-803

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 determine the incidences of overall malignancies, melanoma, non-melanoma skin cancer, basal cell carcinoma, and squamous cell carcinoma in RA and PsA patients enrolled in the SRQ Register and who are receiving abatacept compared to patients who are receiving non-targeted DMARDs and compared to patients receiving targeted DMARDs.

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

- 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

Outcomes

Overall malignancies, melanoma, non-melanoma skin cancer, basal cell carcinoma, and squamous cell carcinoma

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Data analysis plan

Analyses of rates of specified malignancy outcomes - incidence and hazard ratio considering comparators.

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 sources (types)

Other

Data sources (types), other

Exposure 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