

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

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Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/32096>

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 RA and PsA treated with abatacept with a specific look at select malignancies outcomes.

Study status

Ongoing

Research institutions and networks

Institutions

[Aalborg University Hospital](#)

First published: 01/02/2024

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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

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

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

Name of medicine

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

4000

Study design details

Outcomes

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

Data analysis plan

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

Data management

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