Characteristics and Risk Profile of Adult Patients Treated with Apremilast Included in the British Association of Dermatologists Biologic Interventions Register (BADBIR) : A Retrospective Database Analysis (20210230)

First published: 12/04/2022

Last updated: 27/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS46337

Study ID

50015

DARWIN EU® study

No

Study countries

Ireland

United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

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Institution

Multiple centres: 164 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.
medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/12/2017

Study start date

Actual: 12/12/2017

Data analysis start date

Actual: 06/01/2022

Date of final study report

Planned: 01/02/2023

Actual: 01/03/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this study is to describe the profile of patients diagnosed with psoriasis receiving apremilast in routine clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective database study

Study drug and medical condition

Medicinal product name

OTEZLA

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

Patients aged ≥18 years diagnosed with psoriasis treated with apremilast identified from the British Association of Dermatologists Biologic Interventions Register (BADBIR) between October 2015 to March 2021.

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)

Special population of interest

Other

Special population of interest, other

Psoriasis patients

Estimated number of subjects

286

Study design details

Outcomes

Distribution of patients across different severity risk categorization at the time of apremilast initiation. Time from diagnosis of psoriasis to apremilast initiation, time from discontinuation of the most recent prior therapy for psoriasis to apremilast initiation.

Data analysis plan

Continuous variables will be presented with the mean and standard deviation, median and inter-quartile range (IQR), and range. Categorical variables will be presented as the number and proportion in each category. No formal statistical comparisons or significance testing are planned.

Documents

Study results

20210230 Abstract ORSR_Redacted.pdf (352.26 KB)

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

British Association of Dermatologists Biologic Interventions Register (BADBIR)

United Kingdom

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