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





## 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
<b>Last updated:</b> 21/02/2024
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)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)</li>
- 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 stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No