APPRECIATE™ (APREmilast ClinIcAl Treatment Experience in psoriasis): A Multi-center, Retrospective Observational Study of Real-World Experience of Psoriasis Patients Treated with Apremilast in Clinical Dermatology Practice.(20200066 / CC-10004-PSOR-013)

First published: 18/05/2022

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS46882

Study ID

47631

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Croatia
- [ ] Czechia
- [ ] Germany
- [ ] Ireland
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] United Kingdom

Study description

This is a retrospective, multi-center observational cohort study. This study will be implemented first in Germany (approximately 50 sites), the United Kingdom (approximately 20 sites) and Sweden (approximately 25 sites), followed by a selected number of countries in Europe, depending on apremilast local availability. The design of this apremilast retrospective study aims to provide clinical information regarding the treatment initiation and outcomes in psoriasis patients when prescribed apremilast in real world settings. In addition, this study is aiming at capturing physicians' and patients' treatment goals when initiating apremilast and whether these goals are achieved following apremilast use. This study is primarily descriptive in nature, and no a priori hypotheses are specified. Patients must voluntarily sign an informed consent form, be 18 or over, have been diagnosed with plaque psoriasis and have been treated with apremilast during the previous 5-7 months to participate in this study. They must not be involved in any other clinical study involving apremilast.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 133 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: 26/01/2016

Study start date
Actual: 30/06/2016

Data analysis start date
Actual: 27/10/2021

Date of interim report, if expected
Planned: 13/10/2020

Actual: 13/10/2020

Date of final study report
Planned: 31/03/2022

Actual: 07/04/2022

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

Other study registration identification numbers and links

https://clinicaltrials.gov/ct2/show/NCT02740218?cond=NCT02740218&draw=2&rank=1

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Observational study

Data collection methods:

Primary data collection

Main study objective:

The main objective of this study is to describe the treatment patterns and outcomes among apremilast users in routine clinical dermatology practice, from the physician and patient perspective.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

OTEZLA

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

Patients treated for psoriasis with apremilast and their physicians completing questionnaires at 6 (±1) months after initiation of apremilast.

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

610

Study design details

Data analysis plan

Analyses will primarily be performed using descriptive and correlational statistical methods.

Documents

Study results

20200066 ORSR Abstract 20May2022_Redacted.pdf(302.21 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 sources (types)

Other

Data sources (types), other

Electronic Case Report Form (eCRF), and Electronic Data Capture system (EDC)

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