Multicenter Observational study to evaluate the effectiveness of a biosimilar Etanercept (ErelziTM) in patients with established Rheumatic disease previously treated with reference etanercept. (BRONZE)

First published: 03/04/2019

Last updated: 20/01/2025

Study | Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43383

EU PAS number

EUPAS28777

Study ID

43383

DARWIN EU® study

No

Study countries

France

Study description

Study design: National, Multicenter, Prospective, Post-Authorization, non-PASS, Real Life, Observational Study. Primary objective: To evaluate effectiveness of ErelziTM in patients with RA, AS or PsA with, stable clinical response to Enbrel®. Secondary objectives:

• To assess safety in a real-life situation of switching from Enbrel® to ErelziTM.

• To characterize the patient populations and drug utilization patterns of RA, AS and PsA patients who are switched to ErelziTM from stable treatment with Enbrel.

• To assess patient satisfaction at baseline and after switching to ErelziTM.

• To explore what are the factors related (clinical, diagnostic factors, comorbidities, patient therapy history, experience/expertise with biologics, patient-oriented program, clinic location, extent of physician's knowledge of biosimilars) to the physician decision to switch.

Study status

Finalised

Research institutions and networks

Institutions

Sandoz

First published: 01/02/2024

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Institution

Contact details

Study institution contact

placeholder placeholder

Study contact

placeholder@placeholder.com

Primary lead investigator

placeholder placeholder

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2017

Actual: 14/09/2017

Study start date

Planned: 15/02/2019

Actual: 08/02/2019

Data analysis start date

Actual: 31/05/2024

Date of final study report

Planned: 31/08/2023

Actual: 13/12/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SANDOZ FR

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To evaluate effectiveness of ErelziTM in patients with RA, AS or PsA with, stable clinical response to Enbrel®.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

National, Multicenter, Prospective, Post-Authorization, non-PASS, Real Life, Observational Study.

Study drug and medical condition

Name of medicine

ERELZI

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

650

Study design details

Data analysis plan

No minimum number of patients in each disease indication will be required.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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