Tildrakizumab Post-Authorisation Safety Study (PASS) in European Psoriasis Registries (M-14745-40)

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Study Ongoing

Administrative details

EU PAS number

EUPAS37946

Study ID

37947

DARWIN EU® study

No

Study countries

Germany

Ireland

Spain

United Kingdom

Study description

This is a long-term, non-interventional, observational post-authorisation safety study. Using a prospective cohort design, data will primarily be collected in established European registers of patients with psoriasis treated with systemic therapies.

Data from the registers will be used to identify cohorts of patients with psoriasis who initiate treatment with Tildrakizumab, other biologics or non-biologic systemic therapies for psoriasis. Patients will be followed from cohort entry for up to 8 years to determine the incidence of the outcomes of interest.

The registers which will provide data on patient demographics, lifestyle factors (e.g. smoking, alcohol use), comorbidities and medications used to treat them, type of psoriasis, physician and patient assessments of the psoriasis, treatment (pre and current) of psoriasis, any adverse events and safety outcomes in pregnant and lactating women.

Study status

Ongoing

Research institutions and networks

Institutions

Oracle Life Sciences

Contact details

Study institution contact

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Study contact

dsafety@almirall.com

Primary lead investigator

Faber Susanne

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/05/2019

Actual: 29/05/2019

Study start date

Planned: 01/09/2020

Actual: 15/06/2020

Date of final study report

Planned: 01/06/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Almirall S.A.

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of this PASS is to evaluate the long-term safety of Tildrakizumab used for the treatment of patients with moderate to severe psoriasis and to assess whether Tildrakizumab use is associated with an increased risk of malignancies, MACEs, serious infections, suicidal ideation and behavior (SIB), serious hypersensitivity reactions and inflammatory bowel disease (IBD).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post-authorisation safety study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TILDRAKIZUMAB

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

Patients with psoriasis who initiate treatment with Tildrakizumab, other biologics or non-biologic systemic therapies for psoriasis.

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

Immunocompromised

Estimated number of subjects

3.757

Study design details

Outcomes

The primary objectives are to evaluate and compare between patients who initiate treatment with Tildrakizumab and patients who initiate treatment with “other biologics” and between patients who initiate treatment with Tildrakizumab and patients who initiate treatment with “non-biologic systemic therapies” specified risks.

To describe the characteristics of patients with psoriasis who initiate treatment with Tildrakizumab, “other biologics” or “non-biologic systemic therapies” for psoriasis.

To evaluate the incidence of all AEs and all SAEs (other than those covered by the primary objectives), by MedDRA SOCs.

To describe information obtained regarding pregnant and lactating women.

Data analysis plan

Data will be summarised descriptively. There is no a priori hypothesis. For continuous variables, descriptive statistics (number of patients, mean, standard deviation SD, standard error of mean, median, minimum, and maximum) will be provided.

Categorical variables will be analysed by frequency tables (absolute and relative frequencies). Stratified analyses by treatment, dose and registry will be performed. Incidence rates will be calculated during current use of exposure in each respective cohort (i.e. Tildrakizumab, “other biologics” and “non-biologic systemic therapies”). The overall incidence rates of each primary and secondary endpoint (see Section 7.3.2) will be reported. Exact 95% confidence intervals for incidence rates and incidence rate ratios will be calculated (i.e. in accordance with Clopper and Pearson et al. 1934).

In order to account for potential confounding crude and adjusted estimates will be provided, obtained within a multiple regression model.

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

PsoBest Germany, BIOBADADERM Spain, BADBIR United Kingdom, BADBIR Ireland

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