

# 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

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### Study ID

37947

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### DARWIN EU® study

No

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### Study countries

- Germany
  - Ireland
  - Spain
  - United Kingdom
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## 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.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

[Oracle Life Sciences](#)

## Contact details

### Study institution contact

Delia Cristiana Canulescu dsafety@almirall.com

Study contact

[dsafety@almirall.com](mailto: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

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**Study start date**

Planned: 01/09/2020

Actual: 15/06/2020

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**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

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## 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

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

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#### **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

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### **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

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### **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.

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### **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)
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### **Special population of interest**

Immunocompromised

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### **Estimated number of subjects**

3757

## **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.

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### **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

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**Data sources (types)**

[Disease registry](#)

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No