Psoriasis Study of Health Outcomes – an International Observational Study of 3 Year Health Outcomes in the Biologic Treatment of Moderate to Severe Plaque Psoriasis (PSoHO)

**First published:** 30/05/2018

**Last updated:** 02/04/2024





### Administrative details

#### **PURI**

https://redirect.ema.europa.eu/resource/46014

#### **EU PAS number**

**EUPAS24207** 

#### **Study ID**

46014

#### **DARWIN EU® study**

Nο

Study countries	
Argentina	
Australia	
Austria	
Brazil	
Canada	
Colombia	
France	
Germany	
Hungary	
Israel	
Italy	
Korea, Republic of	
Mexico	
Netherlands	
Poland	
Portugal	
Romania	
Saudi Arabia	
Spain	
Switzerland	
Taiwan	
United Arab Emirates	
United Kingdom	

### **Study description**

In order to evaluate the additional benefit of improved skin clearance for patients with psoriasis and the associated long term outcomes including patient reported HRQoL and health care resource consumption, the currently proposed study will explore the clinical effectiveness of anti IL 17A treatments

(specifically ixekizumab and secukinumab) in patients with moderate to severe psoriasis compared to other biologic treatments within routine care.

#### **Study status**

Ongoing

### Research institutions and networks

### Institutions



### Contact details

### **Study institution contact**

Catherine Reed

 $\left(\mathsf{Study}\;\mathsf{contact}\,\right)$ 

reed\_catherine@lilly.com

### **Primary lead investigator**

Catherine Reed

Primary lead investigator

## Study timelines

#### Date when funding contract was signed

Actual: 02/03/2018

### Study start date

Planned: 29/06/2018 Actual: 16/07/2018

#### **Date of final study report**

Planned: 20/11/2023

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

Eli Lilly and Company

## 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 compare the proportion of patients with moderate to severe plaque psoriasis treated in clinical practice with ixekizumab or secukinumab (the anti IL 17A cohort) relative to other biologic treatments who achieve clear or almost clear skin (equivalent to PASI 90 or higher and/or sPGA 0/1) at 12±4 weeks following initiation of or switching to a new biologic

## Study Design

### Non-interventional study design

Cohort

# Study drug and medical condition

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

**IXEKIZUMAB** 

**SECUKINUMAB** 

**BRODALUMAB** 

**USTEKINUMAB** 

**ADALIMUMAB** 

**ETANERCEPT** 

**INFLIXIMAB** 

#### Medical condition to be studied

**Psoriasis** 

## 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**

2000

## Study design details

#### **Outcomes**

PASI, sPGA, BSA, DLQI

#### Data analysis plan

Logistic regression will be used to analyze the proportions of the primary endpoint for assigned anti IL 17A and other biologic treatments. In addition to the treatment groups, the propensity scores derived during baseline interim analyses will be included as covariates into the model.

## Data management

### Data sources

Other	(types)				
Data sources	(types), othe	r			
Prospective pa	ient-based dat	a collectio	n		
Use of a (	Common	Data N	Model (	CDM)	
CDM mapping					
No					
Data qua	ity spacit	fication	2.5		
Data qua	ity specii	icatioi	15		
Check confor		icatioi	15		
•		icatioi	15		
Check confor	nance	icatioi	15		
Check confor	nance	icatioi	15		
Check conford Unknown Check comple	nance teness	icatioi	15		

# Data characterisation

### **Data characterisation conducted**

No