Pregnancy Exposures and Outcomes in Women with Psoriasis Treated with Risankizumab: A Cohort Study Utilizing Large Electronic Healthcare Databases with Mother-Baby Linkage in the United States

First published: 16/03/2021 Last updated: 14/03/2024





### Administrative details

EU PAS number
EUPAS39775
Study ID
47188
DARWIN EU® study
No
Study countries
United States
United States

#### Study description

The study aim is to evaluate the safety of risankizumab during pregnancy in women with psoriasis.

#### **Study status**

Ongoing

### Research institutions and networks

### **Institutions**

### Reagan-Udall Foundation

First published: 01/02/2024

Last updated: 01/02/2024

Institution

### Contact details

### **Study institution contact**

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

### Primary lead investigator

Clinical Trial Disclosure AbbVie

**Primary lead investigator** 

### Study timelines

#### Date when funding contract was signed

Planned: 31/05/2021 Actual: 01/07/2021

#### Study start date

Planned: 31/01/2022 Actual: 21/03/2022

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

Planned: 31/10/2030

# Sources of funding

Pharmaceutical company and other private sector

## More details on funding

AbbVie

### Study protocol

p16751-protocol-pmos abstract-18oct2020\_Redacted.pdf (177.15 KB)

riskmgtsystem-pam-p16751-protocol-pmos\_v1.4\_abstract\_Redacted.pdf (150.93 KB)

# 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)

# Other study registration identification numbers and links

P16-751

# Methodological aspects

# Study type

# Study type list

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

#### Main study objective:

The study aim is to evaluate the safety of risankizumab during pregnancy in women with psoriasis.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

#### Medicinal product name

**SKYRIZI** 

#### Medical condition to be studied

**Psoriasis** 

# Population studied

#### **Age groups**

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

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

Pregnant women

### **Estimated number of subjects**

600

# Study design details

#### **Outcomes**

The primary outcome of this cohort study is major congenital malformations of the infant among live birth pregnancies. Secondary outcomes include the following: • Pregnancy outcomes: live birth, spontaneous abortion, elective abortion, stillbirth • Infant outcomes: premature birth, small for gestational age (SGA), neonatal deaths, serious infections

#### **Data analysis plan**

This study will estimate the incidence (cumulative risks) of pregnancy outcomes, including live births, spontaneous abortions, elective abortion, and stillbirths and will compare the occurrence of these events among risankizumab-exposed women with those among the matched comparator biologic-exposed women. AbbVie will use a log binomial distribution with robust variance using generalized estimating equations to estimate the effects of exposure (cumulative risk ratios and 95% confidence intervals) to risankizumab.

### 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)

Administrative healthcare records (e.g., claims)

# 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