# Characterizing Otezla Use and Exposure Among Pregnant Women (20220012)

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### Administrative details

EU PAS number	
EUPAS46267	
Study ID	
50662	
DARWIN EU® study	
No	
Study countries	
United States	

### **Study status**

Finalised

Research institutions and networks

### **Institutions**

### **Amgen**

☐ United States

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Institution

### Contact details

#### **Study institution contact**

Global Development Leader Amgen Inc. medinfo@amgen.com

Study contact

medinfo@amgen.com

#### **Primary lead investigator**

Global Development Leader Amgen Inc.

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Planned: 31/01/2022

Actual: 31/01/2022

#### Study start date

Planned: 30/03/2022

Actual: 30/03/2022

#### Data analysis start date

Planned: 30/03/2022 Actual: 30/03/2022

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

Planned: 30/09/2022

Actual: 14/10/2022

# Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

Amgen

# Study protocol

Observational Research Study Report 20220012 new\_Redacted.pdf (395.35 KB)

# Regulatory

Was the study required by a regulatory body?

No

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

# Methodological aspects

# Study type

# Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Drug utilisation

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

Secondary use of data

#### Main study objective:

The main objectives of this study are to describe the use and exposure of Otezla among pregnant women, and to estimate the number of infants born linked to women exposed to Otezla during pregnancy.

### Study Design

#### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

Retrospective study

### Study drug and medical condition

#### **Medicinal product name**

**OTEZLA** 

#### Medical condition to be studied

Psoriatic arthropathy

Mouth ulceration

**Psoriasis** 

# Population studied

#### Short description of the study population

The study population included pregnant women aged 16 to 55 years treated with Otezla identified from the IBM Watson Health MarketScan Commercial Claims and Encounters with Medicare Supplemental Research Database (MarketScan) and the UnitedHealth Group Optum Analytics (Optum) database.

#### Age groups

- Adolescents (12 to < 18 years)</li>
- 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**

Pregnant women

#### **Estimated number of subjects**

80

### Study design details

#### **Outcomes**

- Counts and proportions of Otezla use and exposure in the cohort of pregnant women characterized by: • Age • Diagnosis • Calendar year • Number of claims
- Timing of exposure Cumulative probability of descontinuation at 6, 12 and 24 months Counts of live born infants linked to Otezla-exposed pregnancies

#### Data analysis plan

We will estimate the frequency of dosing (number of Otezla claims during pregnancy) and timing of exposure. Among those exposed to Otezla, we will further characterize these patients by age, calendar year of exposure(s), psoriasis, psoriatic arthritis, or Behcet's disease diagnoses. This is a descriptive analysis. Only summary statistics will be produced in the form of numbers and proportions for frequency of doses, timing of exposure, as well as the number of infants linked to exposed pregnancies.

### 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

IBM Watson Health MarketScan Commercial Claims, Encounters with Medicare Supplemental Research Database (MarketScan), the UnitedHealth Group Optum Analytics (Optum) database

#### **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