Characterizing Otezla Use and Exposure Among Pregnant Women (20220012)

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Study Finalised

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.

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Study contact

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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)?

Not applicable

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

Name of medicine

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)

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

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