Evaluation of pregnancy and infant outcomes in Kesimpta patients using PRegnancy outcomes Intensive Monitoring (PRIM) data - The Kesimpta-PRIM study. (The Kesimpta PRIM study.)

First published: 08/12/2022

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Study Ongoing

Administrative details

EU PAS number

EUPAS49855

Study ID

50627

DARWIN EU® study

No

Study countries

☐ Switzerland

Study description

The Kesimpta PRIM study is a secondary use of data, non-interventional study (NIS) based on Novartis' pharmacovigilance (PV) system leveraging data collected via PRIM using a set of targeted checklists with structured follow-up on pregnancies spontaneously reported to the Novartis global safety database (Argus). Although pharmacovigilance data may be collected from any country in the world where the product is approved, the anonymized patient level data will be analyzed at a global level in Switzerland. All prospective and retrospective pregnancy cases reported to Novartis global safety database mentioning exposure to Kesimpta in multiple sclerosis (MS) patients will be considered for this study except cases reported as part of Kesimpta registry study (OMB157G2403). The primary analysis cohort of interest will be the prospectively reported pregnancies associated with maternal exposure during pregnancy up up to 180 days before last menstrual period. Retrospective pregnancy cases are defined as pregnancy cases with known pregnancy outcome or known abnormal findings obtained from a prenatal test at the time of initial reporting to Novartis. The study is descriptive in nature and will apply until a maximum of 10 years from marker authorization or until 500 prospectively reported live births with known status of malformations are assessed, whichever occurs first.

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

Trialandresults.registries@novartis.com

Study contact

Trialandresults.registries@novartis.com

Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/08/2021

Actual: 18/08/2021

Study start date

Planned: 25/09/2022

Actual: 25/09/2022

Data analysis start date
Planned: 31/12/2030

Date of interim report, if expected
Planned: 31/12/2022

Actual: 30/11/2022

Date of final study report
Planned: 30/12/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

COMB157G2407_Protocol V1.1_Redacted.pdf(977.64 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

COMB157G2407

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To estimate the proportion of major congenital malformations associated with exposure to Kesimpta during pregnancy among (i) live births and (ii) live births, stillbirths, and termination of pregnancy for fetal anomaly.

Study drug and medical condition

Name of medicine

KESIMPTA

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

OFATUMUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AA52) ofatumumab

ofatumumab

Medical condition to be studied

Multiple sclerosis

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

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

500

Study design details

Outcomes

Major congenital malformations, Minor congenital malformations Spontanous abortions, stillbirths, elective terminations Adverse birth outcomes: pre-term births, low birth weight, small for gestational age Adverse effects including serious infections (requiring hospitalizations) among infants during the first 12 months after birth

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Data analysis plan

Analysis of Kesimpta-PRIM data will include estimation of proportion (and 95% confidence interval) of malformations (major, minor, and overall), and of specific pregnancy outcomes such as, spontaneous abortions, stillbirths and elective terminations. The proportion of congenital malformations will be calculated amongst: (1) live births and (2) live births, stillbirths and termination of pregnancy for fetal anomaly. Proportion will be estimated overall and by pre specified timing of drug exposure in pregnancy. In addition, major congenital malformations will be summarized by SOC based on the latest available MedDRA classifications. Minor congenital malformations will be listed by preferred term based on the latest available MedDRA classification. The proportion of other adverse birth outcomes associated with exposure to Kesimpta during pregnancy including preterm births, low birth weight and small of gestational age will be estimated among live births.

Data management

Data sources

Data source(s), other

Novartis Global Safety Database Switzerland

Data sources (types)

Other

Spontaneous reports of suspected adverse drug reactions

Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

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