A Worldwide Pregnancy Safety Study to Assess Maternal, Foetal, and Infant Outcomes Following Exposure to Efgartigimod alfa during Pregnancy and/or Breastfeeding

First published: 26/02/2024

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000005

EU PAS number

EUPAS1000000005

Study ID

1000000005

DARWIN EU® study

No

Study countries

☐ European Union

☐ United States

Study description

This is a multi-country, prospective safety study of pregnant women exposed to efgartigimod any time within 25 days prior to conception or any time during pregnancy.

Women exposed to efgartigimod only during breastfeeding will also be eligible to enroll. Background rates of major congenital malformations (MCMs) will be obtained from populations within the same countries/regions as the countries/regions in which the VYVGART IV or SC-exposed pregnancies were reported.

Study status

Ongoing

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

☐ Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Amy Miller

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/01/2023

Study start date

Actual: 14/12/2023

Date of final study report

Planned: 01/06/2034

Study protocol

ARGX-113-PAC-2206-EU Protocol-V2.0_fully signed-including annex4_Redacted.pdf(2.76 MB)

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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Pregnancy exposure registry

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This is a multi-country safety study of pregnant women exposed to efgartigimod during pregnancy or any time within 25 days prior to conception. Infants exposed in utero or through breastfeeding will be followed through 12 months of age.

Main study objective:
This global pregnancy safety study will assess maternal, fetal, and infant outcomes following exposure to efgartigimod during pregnancy and/or breastfeeding.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Pregnancy exposure registry

Study drug and medical condition

Name of medicine
VYVGART

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

Anatomical Therapeutic Chemical (ATC) code
(L04AA58) efgartigimod alfa

efgartigimod alfa

Medical condition to be studied

Myasthenia gravis

Population studied

Short description of the study population

Two mutually exclusive subgroups of the pregnancy safety study population are defined as follows, depending on whether the woman is still pregnant at the time of enrolment.

- Retrospective Pregnancy: woman is no longer pregnant at the time of study enrolment but exposed to efgartigimod any time within 25 days prior to conception or any time during the pregnancy.
- Prospective Pregnancy: woman is pregnant or breastfeeding at the time of study enrolment.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Nursing women

Pregnant women

Estimated number of subjects

279

Study design details

Setting

Two (2) mutually exclusive subgroups of the pregnancy safety study population are defined as follows, depending on whether the woman is still pregnant at the time of enrolment.

- Retrospective Pregnancy: woman is no longer pregnant at the time of study enrolment but exposed to efgartigimod any time within 25 days prior to conception or any time during the pregnancy.
- Prospective Pregnancy: woman is pregnant or breastfeeding at the time of study enrolment.

Comparators

An external historical control will be used as a comparator.

Outcomes

• Pregnancy outcomes: Spontaneous abortion; Elective or therapeutic abortion; Fetal death/stillbirth ; Molar or ectopic pregnancy; Live birth (Preterm delivery; Full term delivery)
• Congenital malformations identified in the developing fetus, neonate, or infant: Major congenital malformations (MCMs); Minor congenital malformations
• Other events of interest identified in the developing neonate and infant (Hospitalizations for serious illness; Potential adverse reactions to medications; Growth and development milestones as described by the Centers for Disease Control and Prevention or other accepted standard assessments; Infant

developmental deficiency; Postnatal growth deficiency or failure to thrive (FTT); Neonatal and infant mortality; Infections; Transient neonatal myasthenia; Vaccination and vaccine reactions

• Maternal complications of pregnancy, including but not limited to: Premature rupture of membranes (PROM); Preterm PROM (PPROM); Pre-eclampsia; Gestational hypertension; Eclampsia; Proteinuria; Gestational diabetes; Intrauterine growth restriction (IUGR); Polyhdramnios

• Maternal infections

• Measures of fetal growth deficiency (e.g., small for gestational age)

Data management

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

Unknown