Tafamidis Pregnancy Surveillance Study

First published: 09/09/2020
Last updated: 23/04/2024

Study | Ongoing

Administrative details

PURI
https://redirect.ema.europa.eu/resource/47046

EU PAS number
EUPAS37119

Study ID
47046

DARWIN EU® study
No

Study countries
Canada
France
Germany
Japan
Portugal
Spain
United Kingdom
United States

Study description
This descriptive non-interventional study of women diagnosed with ATTR exposed to tafamidis during or within 1 month prior to pregnancy is intended to assess the risks of pregnancy outcomes and adverse effects on the developing fetus, neonate and infant.

Study status
Ongoing

Research institution and networks

Institutions

Pfizer
First published: 01/02/2024
Last updated 01/02/2024
Institution

Contact details

Study institution contact
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Study contact

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Primary lead investigator
Ebede Ben
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
28/04/2020
Actual:
28/04/2020

Study start date
Planned:
30/04/2020
Actual:
22/06/2020

Date of interim report, if expected
Planned:

30/04/2021

Date of final study report
Planned:
31/12/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Non-EU RMP only

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:
Birth outcome frequency within the reported pregnancies (live full term or premature birth, spontaneous or induced abortion, and stillbirth) in women with ATTR exposed to tafamidis

during or within 1 month prior to pregnancy, frequency of reported fetal, neonate and infant outcomes within the reported pregnancies.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Non-interventional surveillance study

Study drug and medical condition

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

Medical condition to be studied
Acquired ATTR amyloidosis

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)

Special population of interest
Pregnant women

Estimated number of subjects
50

Study design details

Data analysis plan
No formal data analysis or hypothesis testing will be conducted. Data collected on exposures and outcomes will be summarized descriptively.

Data management

Data sources (types)
Administrative data (e.g. claims)
Disease registry
Electronic healthcare records (EHR)
Spontaneous reporting system
Other

Data sources (types), other
Prescription event monitoring

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