THE SAVELLA® PREGNANCY REGISTRY (MLN-MD-30 / CMO-EPI-NEU-0539)

First published: 09/03/2018

Last updated: 25/03/2025

Study Finalised

Administrative details

EU PAS number

EUPAS22236

Study ID

35070

DARWIN EU® study

No

Study countries

☐ United States

Study description

This is a prospective, observational, exposure-registration and follow-up registry of women and their offspring exposed to Savella during pregnancy and among infants during the first year of life.

Study status

Finalised

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 08/07/2009

Study start date
Actual: 04/12/2009

Date of final study report
Actual: 31/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan plc

Study protocol

Savella MLN-MD-30 Protocol EUPAS .pdf(271.73 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

NCT01026077

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective is to estimate the prevalence of major congenitalanomalies among offspring of women exposed to Savella duringpregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Savella

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

350

Study design details

Outcomes

To estimate the prevalence of major congenital anomalies among offspring of women exposed to Savella during pregnancy.

To estimate the prevalence of full-term live births (at least 37 weeks), pre-term live births (<37 weeks), recognized spontaneous abortions, stillbirths, induced abortions (elective and therapeutic), chromosomal abnormalities, and minor congenital anomalies

To summarize- Serious pregnancy complications and maternal adverse events- Adverse pregnancy outcomes- Serious adverse outcomes

Data analysis plan

The intent of the Registry is to determine whether there is a signal that might indicate a potential risk for major birth defects in the offspring of women following exposure to Savella during pregnancy.
Therefore, it is necessary to monitor the cumulative data to detect potential signals or patterns, to evaluate them, and to determine the necessary course of action when a signal is noted.

Documents

Study results

CMO-EPI-NEU-0539 CSR Synopsis.pdf(204.62 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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