A Registry of Patients Treated with Fintepla (TAPESTRY Registry)

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Study Ongoing

Administrative details

EU PAS number

EUPAS105358

Study ID

105359

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Spain

United Kingdom

Study description

This observational, multi-country, cohort study (a registry) will assess the long-term cardiac safety of fenfluramine as prescribed in routine clinical practice for fenfluramine approved indications, with focus on incidence of valvular heart disease (VHD) and incidence of pulmonary arterial hypertension (PAH).

Study status

Ongoing

Contact details

Study institution contact

Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available. clinicaltrials@ucb.com

Study contact

clinicaltrials@ucb.com

Primary lead investigator

Clinical Trial Registries and Results Personal data of lead investigator will not be disclosed because his/her consent required for disclosure according to applicable data protection laws is not available.

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/09/2022

Study start date
Actual: 09/06/2023

Date of final study report
Planned: 02/01/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Zogenix International Ltd. (now part of UCB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/C/003933

Other study registration identification numbers and links

ZX008-2101 (EP0218)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

Assess the long-term cardiac safety of fenfluramine as prescribed in routine clinical practice for fenfluramine approved indications, with a focus on (1) Incidence of valvular heart disease (VHD) and (2) Incidence of pulmonary arterial hypertension (PAH)

Study Design

Non-interventional study design

Other

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AX26) fenfluramine

fenfluramine

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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)

Estimated number of subjects

600

Study design details

Outcomes

The primary outcome variables for all patients will include but not be limited to: 1) Date of ECHO 2) Grade (absent/trace, mild, moderate, severe) of valve regurgitation and affected valves 3) Presence or absence of elevated PASP (equal to or more than 35 mm Hg) 4) Valvular or any other abnormality reported on baseline ECHO. They are further described in protocol section 9.3.1. The secondary outcome variables are related to growth retardation and echocardiographic monitoring characteristics. They are further described in protocol section 9.3.2.

Data analysis plan

The analyses will be descriptive. Continuous variables will be described by the number of valid cases and missing data, mean, standard deviation, median, first quartile, third quartile, minimum, and maximum. Categorical variables will be described as the total number and relative percentage per category. 95% confidence intervals (CIs) will be calculated when relevant. There will be no imputation of missing data. Incidence rates will be calculated by dividing the number of new cases (up to the first event) of VHD or PAH by the number of person-years at risk.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

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