A non-interventional study to assess the long-term safety and efficacy of osilodrostat in patients with endogenous Cushing’s syndrome (LINC 6)

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Study Ongoing

Administrative details

EU PAS number

EUPAS46496

Study ID

46497

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ Italy

United States

Study description

Osilodrostat received approval from the EMA on 9-Jan-2020 for the treatment of adult patients with endogenous Cushing’s syndrome (CS). FDA approval was achieved on 6-Mar-2020 for the treatment of adult patients with Cushing’s disease (CD) for whom pituitary surgery is not an option or has not been curative. The Japanese Ministry of Health, Labour and Welfare (MHLW) approved osilodrostat for the treatment of patients with endogenous Cushing’s syndrome for whom pituitary surgery is not an option or has not been curative on 24th March 2021. The clinical development programme of osilodrostat provided robust data on the efficacy and safety of the compound, at the same time, the management of patients with endogenous Cushing’s syndrome requires life-long treatment. Therefore, this non-interventional study will assess the long-term safety of osilodrostat. In addition, the long-term use will also be evaluated in non-CD CS patients.

Study status

Ongoing

Research institutions and networks

Institutions

Recordati

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Institution

Hopital de la Conception - APHM Marseille, France, Hopital Larrey Toulouse, France, CHU de Nancy - Hôpital de Brabois Nancy, France, Groupement Hospitalier Sud - Hôpital Bicêtre Bicetre, France, Hôpital Cochin Paris, France, CHU Bordeaux - Hôpital Haut-Lévêque Pessac, France, Hôpital Cardio-Vasculaire et Pneumologique Louis Pradel Bron, France, Hopital Claude Huriez - CHRU Lille Lille, France, CHU de Nantes-Hopital Laennec Nantes, France, Other hospitals in France, Germany, Italy and USA France, Germany, Italy, USA

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Juergen Fleck

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/12/2021

Study start date

Planned: 04/07/2022

Actual: 13/06/2022

Data analysis start date

Planned: 14/08/2028

Date of final study report

Planned: 31/05/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Recordati AG

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Safety study (incl. comparative)

Main study objective:

The main objective of the study is to further document the long-term safety and tolerability profile of osilodrostat in routine clinical practice over a 3-year follow-up period when administered as monotherapy or in combination with other therapies in patients with endogenous Cushing's Syndrome.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Drug interaction study

Study drug and medical condition

Name of medicine

ISTURISA

Medical condition to be studied

Cushing's syndrome

Population studied

Age groups

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

100

Study design details

Outcomes

The primary outcome is the incidence of osilodrostat-related adverse events and serious adverse events during the 3 years of treatment with osilodrostat. Particular focus is on the Adverse Events of Special Interest (AESI) and Other Reportable Information (ORI). Short and long-term efficacy of osilodrostat, change in biochemical measures of disease activity, normalisation of biochemical measures of disease activity, change in cardiovascular- and metabolic-related parameters, change in physical features of the disease, changes in pituitary tumour size, changes in patient-reported outcome questionnaires, overall safety and tolerability of osilodrostat.

Data analysis plan

The main goal is to further document the long-term safety and tolerability profile of osilodrostat by measuring the incidence of the safety events: o Related Adverse Events o Serious Adverse Events o Adverse Events of Special Interest o Other Reportable Information All safety summaries will show the number of AEs and the number and percentage of patients experiencing at least one event by AE category (All, related AEs, SAEs, AESI and ORI). In the secondary analyses, measurements will be presented using summary statistics, and may also be reported by looking at the change from baseline (actual and percentage) over time. For Quality of Life questionnaires, descriptive statistics including change from baseline will be presented over time. For all summary tables presented over time, time windows as defined in the SAP, will be applied.

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