A Retrospective Cohort Study for Estimating Incidence Rates of Infusion Site Events for ABBV-951 for the Treatment of Advanced Parkinson's Disease

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000050

EU PAS number
EUPAS1000000050

Study ID
1000000050

DARWIN EU® study
No

Study countries
Finland
France

Study description
The overall aim of this study is to evaluate the effectiveness of additional risk minimization measures (aRMM) by estimating incidence rates of infusion site events (i.e., infusion site infections and/or serious infusion site reactions) in Parkinson disease (PD) patients exposed to ABBV-951 in real-world clinical practice, using data sources from Finland and France. The frequency of infusion site events observed in this real-world study will be interpreted in context of the predefined reference value which is the frequency of the

infusion site events reported in the AbbVie clinical trial. The following objectives will be investigated among patients with advanced PD following initiation of treatment with ABBV-951:

• To quantify the incidence rate of first infusion site events (first infusion site infection OR first serious infusion site reactions)
• To quantify the incidence rate of first infusion site infection
• To quantify the incidence rate of first serious infusion site reaction

Study status
Planned

Research institution and networks

Institutions

Global Database Studies (GloDaSt), IQVIA

Czechia
Finland
Germany
Slovakia
Spain
First published: 17/01/2011
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16/02/2024
Institution
ENCePP partner
Other

AbbVie

Contact details

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Study contact

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Primary lead investigator

Valeria Saglimbene
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
01/11/2022
Actual:
03/11/2022

Study start date
Planned:
01/06/2025

Data analysis start date
Planned:
01/09/2027

Date of final study report
Planned:
01/03/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie Inc.

Study protocol

P24151-Protocol v1.0_Redacted.pdf(1.24 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

Data collection methods:
Secondary data collection

Study design:
A longitudinal, retrospective cohort study of individuals with advanced PD treated with ABBV-951 in Finland and France. The overall study period will be from the date of market availability (anticipated Q4 2023) until Q1 2027. Index date will be defined as the date of first initiation of ABBV-951.

Main study objective:
• To quantify the incidence rate of first infusion site event (first infusion site infection OR first serious infusion site reaction)
• To quantify the incidence rate of first infusion site infection
• To quantify the incidence rate of first serious infusion site reaction

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Name of medicine, other
Foslevodopa/Foscarbidopa

Medical condition to be studied
Parkinson's disease

Population studied

Special population of interest
Immunocompromised
Other

Special population of interest, other
Diabetes Mellitus

Study design details

Outcomes
• Infusion site event (first occurrence only) defined as infusion site infection OR serious infusion site reaction
• Infusion site infection (first occurrence only)
• Serious infusion site reactions (first occurrence only)

Data management

Data sources

Data source(s)
Système National des Données de Santé (French national health system main database)
Longitudinal Patient Data - France
Terveydenhuollon hoitoilmoitusrekisteri (Care Register for Health Care)

Data source(s), other
PMSI == Programme de Médicalisation des Systèmes d'Information;
AvoHILMO = Register of Primary Health Care Visits;
Finnish EMR;
Prescription Registers Finland.

Data sources (types)
Administrative data (e.g. claims)
Drug dispensing/prescription data
Electronic healthcare records (EHR)

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