Post Marketing Surveillance on Long Term Use of JARDIANCE® Tablets in Patients with Chronic Kidney Disease in Japan

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000279

EU PAS number

EUPAS1000000279

Study ID

1000000279

DARWIN EU® study

No

Study countries

☐ Japan

Study status

Planned

Contact details

Study institution contact

Akiko Ito

Study contact

akiko.ito@boehringer-ingelheim.com

Primary lead investigator

Akiko Ito

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/08/2024

Study start date

Planned: 01/09/2024

Date of final study report

Planned: 30/04/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

Study protocol

observational and non-interventional study protocol 1245-0340_V1.0_redacted.pdf(406.85 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Study design:

Cohort study

Non-interventional, single arm study based on newly collected data Patients will be observed for up to 52 weeks after the start of the treatment with JARDIANCE® Tablets or until discontinuation of administration.

Main study objective:

Study objective is to investigate the safety and effectiveness of long-term daily use of JARDIANCE® Tablets in patients with CKD under real-world use.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

JARDIANCE

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

EMPAGLIFLOZIN

Anatomical Therapeutic Chemical (ATC) code

(A10BK03) empagliflozin

empagliflozin

Medical condition to be studied

Chronic kidney disease

Population studied

Special population of interest

Renal impaired

Estimated number of subjects

1000

Data management

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