Post Marketing Surveillance in Japan on Long Term Drug Use of TRADIANCE® Combination Tablets AP and BP in Patients with type 2 Diabetes Mellitus (Japanese TRADIANCE PMS, long term)

First published: 07/11/2018

Last updated: 05/04/2022

Study Finalised

Administrative details

EU PAS number

EUPAS26442

Study ID

46569

DARWIN EU® study

No

Study countries

☐ Japan

Study description

Study objective is to investigate the safety of long-term daily use of TRADIANCE® Combination Tablets AP and BP in Japanese patients with type 2 Diabetes Mellitus under real-world use.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 200 centres are involved in the study

Contact details

Study institution contact

Naoki Shimmoto zzCDMJP_PV_PMS@boehringer-ingelheim.com

Study contact

zzCDMJP_PV_PMS@boehringer-ingelheim.com

Primary lead investigator

Naoki Shimmoto

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/09/2018

Actual: 07/11/2018

Study start date

Planned: 15/01/2019

Actual: 15/01/2019

Data analysis start date

Planned: 01/06/2021

Actual: 01/06/2021

Date of final study report

Planned: 31/03/2022

Actual: 11/12/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd., Eli Lilly Japan K.K.

Regulatory

Was the study required by a regulatory body?

No

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

Study objective is to investigate the safety of long-term daily use of TRADIANCE® Combination Tablets AP and BP in Japanese patients with type 2 Diabetes Mellitus under real-world use.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional, prospective, observational, single arm

Study drug and medical condition

Medical condition to be studied

Type 2 diabetes mellitus

Population studied

Short description of the study population

Patients with type 2 Diabetes Mellitus.

Age groups

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)

Special population of interest

Other

Special population of interest, other

Type 2 diabetes mellitus patients

Estimated number of subjects

1200

Study design details

Outcomes

Incidences of adverse drug reactions

Data analysis plan

Analyses are descriptive in nature, including confidence intervals. Due to the nature of the observational study, no confirmatory statistical testing is foreseen in this study.Subgroup analyses are also performed if sample size allows.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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