

A regulatory requirement non interventional study to monitor the safety and effectiveness of JARDIANCE® (empagliflozin 10mg, 25mg) in Korean patients with type 2 diabetes mellitus (JARDIANCE® rPMS in Korean patients with T2DM)

**First published:** 31/05/2016

**Last updated:** 17/05/2018

Study

Ongoing

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/24002>

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### **EU PAS number**

EUPAS13627

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### **Study ID**

24002

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## DARWIN EU® study

No

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### Study countries

Korea, Republic of

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### Study description

To monitor the safety profile and effectiveness of Empagliflozin in Korea patients with type 2 diabetes mellitus in a routine clinical practice setting

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### Study status

Ongoing

## Research institutions and networks

### Institutions

[Boehringer Ingelheim](#)

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**Institution**

## Contact details

### Study institution contact

Taylor Choi

**Study contact**

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### **Primary lead investigator**

DaeWook Lee

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 10/06/2016

Actual: 05/07/2016

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### **Study start date**

Planned: 30/07/2016

Actual: 11/08/2016

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### **Data analysis start date**

Planned: 11/06/2020

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### **Date of final study report**

Planned: 11/11/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## Regulatory

## Was the study required by a regulatory body?

Yes

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

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

## Methodological aspects

### Study type

### Study type list

#### Study type:

Non-interventional study

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#### Scope of the study:

Effectiveness study (incl. comparative)

Other

#### If 'other', further details on the scope of the study

Safety monitoring

#### Main study objective:

To monitor the safety profile and efficacy of JARDIANCE® (empagliflozin, 10mg, 25mg) in Korean patients with type 2 diabetes mellitus in a routine clinical practice setting

## Study Design

## **Non-interventional study design**

Cohort

# Study drug and medical condition

## **Name of medicine**

JARDIANCE

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## **Medical condition to be studied**

Type 2 diabetes mellitus

# 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)

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## **Estimated number of subjects**

3000

# Study design details

## **Outcomes**

1) PRIMARY OBJECTIVE To monitor the safety profile and effectiveness of Empagliflozin in Korea patients with type 2 diabetes mellitus in a routine clinical

practice setting, 2) SECONDARY OBJECTIVE(1) Change from baseline in HbA1c after 12 weeks and/or 24 weeks of treatment(2)Occurrence of treat to target effectiveness response that is an HbA1c under treatment of < 7% after 12 weeks and/or 24 weeks of treatment(3) Occurrence of relative effectiveness response (HbA1c lowering by at least 0.5% after 12 weeks and/or 24 weeks)

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### **Data analysis plan**

1)Analysis of demographic data:Demographic data and the health status of subjects for the safety evaluation will be analysed descriptively.For continuous data, mean, standard deviation, minimum value, and maximum value will be described, while for categorical data, frequency will be shown.2)Safety analysis: In the safety assessment population, the number of subjects to whom AE occurred and the number of AEs will be calculated. Also, the incidence proportion of AEs will be estimated with its 95%confidence interval.3)Efficacy analysis: Mean,standard deviation,minimum value,maximum value,and median of changes in glycosylated hemoglobin and fasting plasma glucose,body weight,and blood pressure, which were measured at the last visit versus baseline, should be presented, and if there is difference before administration versus after administration should be analyzed using paired t-test. The number and percentage of subjects for final efficacy evaluation

## Data management

### Data sources

#### **Data sources (types)**

Other

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## **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No