Boehringer Ingelheim

Clinical Study Synopsis for Public Disclosure

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A synopsis is not intended to provide a comprehensive analysis of all data currently available regarding a particular drug. More current information regarding a drug is available in the approved labeling information which may vary from country to country..

Additional information on this study and the drug concerned may be provided upon request based on **Boehringer Ingelheim's Policy on Transparency and Publication of Clinical Study Data**.

ABSTRACT

Name of company: Boehringer Ingelheim Korea Ltd.			
Name of finished medicinal product: JARDIANCE®			
Name of active ingredient: Empagliflozin			
Report date:	**Study number:**	**Version/Revision:**	**Version/Revision date:**
04MAR2026	1245-0323	1.0	NA
Title of study:	A regulatory non-interventional study to monitor the safety and efficacy of JARDIANCE® (Empagliflozin 10 mg) in Korean patients with Chronic Kidney Disease (CKD)		
Keywords:	JARDIANCE, Safety, Efficacy, Post-marketing surveillance, Korean		
Rationale and background:	This post-marketing surveillance (PMS) was conducted as a local post-authorization safety study (PASS) in accordance with Korean PMS regulations. Under these regulations, the marketing authorization holder (MAH) is required to perform a study during the re-examination period to collect, review, and verify information on the safety and efficacy of newly approved drugs subject to re-examination. The real-world data (RWD) generated from this study is submitted to the Ministry of Food and Drug Safety (MFDS), the outcomes will be reflected in the product labeling. MFDS approved chronic kidney disease (CKD) as a new indication for Jardiance. As part of the risk management plan (RMP), a mandatory post-authorization study was required to collect safety data from 250 patients over a two-year period in routine clinical practice. Although the safety profile of JARDIANCE had been established through controlled clinical trials, real-world clinical settings involve patients with broader demographic and clinical characteristics than those enrolled in trials. Therefore, this study was designed to provide additional evidence to confirm and monitor the safety of JARDIANCE in Korean patients with CKD under real-world conditions.		
Research question and objectives:	To monitor the safety profile and efficacy of JARDIANCE in Korean patients with CKD in routine clinical practice.		
Study design:	Single-arm, open-label, multicenter, observational, non-interventional study		
Setting:	For patients diagnosed with CKD in Korea, the Kidney Disease: Improving Global Outcomes (KDIGO) criteria were made available as a reference for determining the diagnosis.		

	Inclusion criteria: • Patients aged 19 years or older at the time of enrollment • Patients diagnosed with CKD • Patients with CKD starting JARDIANCE for the first time in accordance with the approved label in Korea • Patients who have provided informed consent and signed the data release consent form Exclusion criteria: • Patients with prior exposure to JARDIANCE • Patients with hypersensitivity to empagliflozin or to any of the excipients • Patients with type 1 diabetes • Patients with a history of diabetic ketoacidosis • Patients with rare hereditary conditions of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption • Patients who are pregnant or breastfeeding, or who plan to become pregnant during the study period
Subjects and study size, including dropouts:	Total number of enrolled patients: 299 • Number of safety set: 273 (long-term safety set: 243) • Number of efficacy set: 92 (long-term efficacy set: 79) * Target number of patients: 250 (safety set)
Variables and data sources:	**Primary outcomes** The primary outcomes are the safety outcomes calculated as the incidence of: • Adverse events (AEs) • Serious adverse events (SAEs) • Non-serious adverse events (Non-SAEs) • Adverse drug reactions (ADRs) • Serious adverse drug reactions (SADRs) • Unexpected adverse events (UAEs) • Adverse events of special interests (AESIs) • Specific adverse events (Specific AEs) • AEs leading to temporary or permanent discontinuation • AEs by intensity • AEs by outcome of the events • AEs by causality • AEs leading to death **Secondary outcomes** The secondary outcome is the efficacy outcome as follows:

	• Change in urine albumin-creatinine ratio (UACR) from baseline after 12 weeks and/or 24 weeks of treatment **Data source:** Patients' medical records
Results:	During the re-examination period, analysis of the demographics of the 273 patients in the safety set showed a mean age (standard deviation) of 56.3 years (15.72), with an age range of 19 to 88 years. The gender distribution showed 63.37% male (173/273 patients) and 36.63% female (100/273 patients), with a higher proportion of males. The incidence of AEs reported in the safety set (n = 273) was 16.85% (46/273 patients; 54 events). The incidence of ADRs for which causality with this drug could not be excluded was 3.66% (10/273 patients; 11 events). The incidence of SAEs was 2.20% (6/273 patients; 7 events), and no SADRs for which causality with this drug could not be excluded were reported. The incidence of UAEs was 5.49% (15/273 patients; 17 events), and among these, the incidence of UADRs for which causality with this drug could not be excluded was 0.73% (2/273 patients; 2 events). The incidence of USAEs was 1.83% (5/273 patients; 6 events). The incidence of Non-SAEs was 15.38% (42/273 patients; 47 events). No AESIs were reported. The incidence of specific AEs was 0.73% (2/273 patients; 2 events), and the incidence of AEs leading to permanent discontinuation was 2.56% (7/273 patients; 7 events). No AEs leading to temporary discontinuation or death were reported. When all AEs reported during this re-examination period were classified by intensity, 'Mild' was reported in 11.72% of patients (32/273 patients; 37 events), followed by 'Moderate' in 4.76% (13/273 patients; 14 events), and 'Severe' in 1.10% (3/273 patients; 3 events). During the re-examination period, the incidence of AEs reported in the geriatric population (age ≥ 65 years; n = 103) was 24.27% (25/103 patients; 30 events). Among these, the incidence of ADRs was 3.88% (4/103 patients; 4 events). The incidence of SAEs was 4.85% (5/103 patients; 6 events), and no SADRs were reported. The incidence of UAEs was 7.77% (8/103 patients; 10 events), and no unexpected ADRs (UADRs) were reported. The incidence of specific AEs was 1.94% (2/103 patients; 2 events), and AEs leading to permanent discontinuation of JARDIANCE were reported in 2.91% of patients (3/103 patients; 3 events). In patients with hepatic impairment (n = 32), the incidence of AEs was 18.75% (6/32 patients; 10 events), and no ADRs were reported. The

incidence of SAEs was 9.38% (3/32 patients; 4 events), and the incidence of UAEs was 6.25% (2/32 patients; 3 events); all of these events were classified as USAEs. The incidence of specific AEs was 3.13% (1/32 patients; 1 event), and AEs leading to permanent discontinuation of JARDIANCE were reported in 3.13% of patients (1/32 patients; 1 event).

In the long-term safety set (n = 243), the incidence of AEs was 14.40% (35/243 patients; 42 events). Among these, the incidence of ADRs for which causality with this drug could not be excluded was 2.06% (5/243 patients; 6 events).

To identify factors affecting safety outcomes, multiple logistic regression analysis was performed. Age (odds ratio = 1.0438; 95% CI: 1.0026–1.0867; p = 0.0369) demonstrated statistical significance in relation to AE incidence. However, although the 95% confidence interval (CI) slightly exceeded 1 and therefore showed statistical significance, the effect size was very small. Thus, the impact of increasing age on the occurrence of AEs is considered to be clinically limited.

Meanwhile, geriatric population (age ≥ 65 years; odds ratio = 0.7407; 95% CI: 0.2452–2.2375; p = 0.5946) was not identified as a statistically meaningful factor. These results suggest that although age may be a potential risk factor, the actual increase in risk observed in this study was minimal.

In the efficacy set (n = 92), analysis of the change from baseline in UACR after 12 and/or 24 weeks of JARDIANCE treatment showed that the mean change at Week 12 was –163.65 mg/g (standard deviation [SD]: 474.780) (p = 0.0033), demonstrating a statistically significant reduction. At Week 24, the mean change (SD) was –30.35 mg/g (455.083) (p = 0.4276), indicating no statistically significant difference.

In the efficacy set (n = 92), the overall efficacy assessment showed that 64.13% (59/92 patients) were evaluated as “Improved”, 20.65% (19/92 patients) as “Unchanged,” and 15.22% (14/92 patients) as “Aggravated”. Based on the classification criteria in which cases evaluated as “Improved” were categorized as “Efficacy”, and those evaluated as “Unchanged” or “Aggravated” were categorized as “Inefficacy”, the efficacy rate of JARDIANCE was 64.13% (59/92 patients), and the inefficacy rate was 35.87% (33/92 patients).

In the long-term efficacy set (n = 79), the change from baseline in UACR after 12 and/or 24 weeks of JARDIANCE treatment, as well as the overall efficacy assessment, was consistent with those observed in the efficacy set.

During the re-examination period, analysis of differences in the overall efficacy rate showed no factors affecting efficacy.

In this study, although the degree of reduction in UACR tended to lessen over time following JARDIANCE treatment, an overall decreasing trend

	was maintained. These results may be interpreted as showing a direction consistent with a key therapeutic objective in CKD—to slow the progression of renal function decline.
Discussion:	According to this post-marketing surveillance of JARDIANCE, no particular trends warranting close attention were identified with respect to safety or efficacy, and no new information was observed that would meaningfully affect the benefit–risk assessment. As part of its ongoing safety surveillance and management plan, Boehringer Ingelheim will continue to monitor and collect spontaneous reports and relevant study findings to identify factors affecting safety, thereby ensuring comprehensive safety management of the product.
Marketing Authorisation Holder(s):	Boehringer Ingelheim Korea
Names and affiliations of principal investigators:	[redacted]

Study Site	Principal Investigator
[redacted]	[redacted]