BORYUNG Pharmaceutical

SYNOPSIS

Protocol No.	BR-FMS-PASS-401
Sponsor	Boryung Pharmaceutical Co., Ltd.
Active Ingredient Name	Fimasartan potassium trihydrate
Study Title	A Prospective, Observational, Post-Authorization Long-term Safety Surveillance on Antihypertensive Treatment With Kanarb® (Fimasartan) During 1 Year Among 20 and Older Diagnosed With Essential Hypertension
Study Objectives	Primary Objective: To evaluate the incidence and characteristics (profile, relationship to the study drug, severity, and outcome) of adverse events (AEs) observed during 1-year treatment with Kanarb tablet® (fimasartan) Secondary Objectives: To investigate the rates of discontinuation and persistence of 1-year treatment with Kanarb tablet® (fimasartan) (including the investigation of the rates of switching to other drugs and concomitant administration with other antihypertensive drugs)
No. of Subject	Target number of subjects: 600 subjects
Inclusion Criteria	1. Patients with essential hypertension 2. Taking Kanarb tablet® (fimasartan) as prescribed previously (within 1 month) or newly 3. Male and female adults aged 20 years or older 4. Voluntarily provided a written consent to participate in the study
Exclusion Criteria	Meeting any of the following including contraindications for fimasartan 1. Patients with hypersensitivity to this drug or the ingredients of this drug 2. Pregnant or breast-feeding women 3. Patients on renal dialysis 4. Patients with moderate to severe hepatic impairment 5. Patients with biliary atresia 6. Genetic disorders such as galactose intolerance, lapp lactase deficiency, or glucose-galactose malabsorption 7. Patients considered inappropriate for taking Kanarb tablet® (fimasartan) by investigator 8. Clinically significant abnormal liver function (AST, ALT ≥2 x upper limit of normal (ULN); TB ≥1.5 ULN)
Statistical Analysis Method	Incidence of adverse events (AEs), treatment persistence rate and treatment discontinuation rate of fimasartan were reported for each measurement time point and their 95% confidence intervals were presented