▣ Protocol Synopsis

Study Title	A multi-center, open, longitudinal, observational study to assess the treatment trend and the proportion of target blood pressure attainment in patients whose antihypertensive regimens are changed to angiotensin II receptor blocker-based therapy Study Short Title: FRESH study_**F**imasa**R**tan-bas**E**d BP Targets after Drug **S**witc**H**ing
Sponsor	Boryung Pharmaceutical Co., Ltd.
Study Objectives	The recent hypertension clinical practice guidelines published by American College of Cardiology (ACC) and American Heart Association (AHA) reduced the target BP to 130/80 mmHg, indicating the needs for more aggressive efforts in hypertension treatment. However, studies in Koreans must be preceded before applying such new overseas guidelines; thus, this study has been designed to establish clinical materials reflecting treatment setting in Korea. In this study, patients with uncontrolled hypertension whose antihypertensive regimens are changed to ARB-based therapy (ARB monotherapy or ARB-containing combination therapy) will be followed to assess the treatment trend, treatment effect, and risk of cardiovascular disease.
Sample Size	Approximately 5,000 subjects
Subject Inclusion Criteria	① Provided written consent to the use of personal information after receiving the explanation of the objective, methodology, etc. of this clinical study ② Male or female adults ≥ 19 years who are diagnosed with essential hypertension ③ Receiving outpatient treatment at the time of study enrollment ④ Patients with hypertension uncontrolled by existing antihypertensive drugs (including ARB) whose antihypertensive regimens decided and scheduled to be changed to ARB monotherapy or ARB-containing combination therapy (the result of the arm with a higher mean BP [systolic BP preferred] when measured twice with at least a 2-minute interval in both arms at the medical office on the study enrollment date, will become the reference) ➢ Definition of uncontrolled hypertension: Target BP (SBP <140 mmHg and DBP <90 mmHg) not achieved even after the treatment using the existing antihypertensive drugs for 4 weeks or longer
Subject Exclusion Criteria	① Patients who were hospitalized or are scheduled to be hospitalized 4 weeks before or after the study enrollment date ② Patients with suspected or confirmed secondary hypertension ③ Pregnant or breast-feeding women ④ Patients who received investigational product within 12 weeks or are scheduled to participate in another clinical study while participating in this study ⑤ Patients who are determined inappropriate for participating in the study by investigators for other reasons
Statistical Analysis Methods	<u>Analysis of Primary Endpoints</u> Frequency and proportion of patients who attain the target BP at Week 12 after the treatment regimen change will be calculated and the 95% confidence interval for the

	proportion will be provided. Analysis of Safety Data ・ Incidence and characteristics of antihypertensive drug related adverse drug reactions For adverse drug reactions (ADRs) related to antihypertensive drugs, the number of subjects, incidence, 95% confidence interval for the incidence, and number of cases will be provided. ・ Serious adverse events/adverse drug reactions For serious adverse events and serious adverse drug reactions, the number of subjects, incidence, 95% confidence interval for the incidence, and number of cases will be provided.