4. ABSTRACT

Name of company: Nippon Boehringer Ingelheim Co., Ltd.			
Name of finished medicinal product: Micatrio® Combination Tablets			
Name of active ingredient: Telmisartan (C09CA07) / amlodipine (C08CA01) / hydrochlorothiazide (C03AA03)			
Protocol date: 12 December 2016	**Study number:** 1348.6	**Version/Revision:** 2.0	**Version/Revision date:** 16 October 2015
Title of study:	The special drug use-results survey on long-term use of telmisartan 80 mg/amlodipine 5 mg/hydrochlorothiazide 12.5 mg fixed dose combination tablets in Patients with Hypertension Trial Clinical Monitor : Rie Ikeda (Pharmacovigilance)		
Rationale and background:	The Japanese Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical requires accumulating safety and effectiveness data of launched products in Japan for re-examination. The PMS plan is a part of the J-RMP. The J-RMP was submitted to the PMDA as a part of J-CTD and need to be approved by PMDA as approval condition. After 4 or 6 years from approval, the results of the PMS are needed to be submitted to the Japanese regulatory authority, the PMDA, as a part of the re-examination dossier.		
Research question and objectives:	This PMS is designed to investigate the safety, effectiveness and appropriate use of Micatrio® Combination Tablets in patients with hypertension under real-world use according to the Japanese package insert.		
Study design:	Non-interventional study based on newly collected data. The study will consist of a baseline visit and follow-up visits at Week 4, 8, 12, 24, 36 and 52 for patients who have newly initiated Micatrio® Combination Tablets. The patients will be followed up until discontinuation of Micatrio® Combination Tablets treatment or the end of study. All patients administrated Micatrio® Combination Tablets after the launch at the sites contracted with the sponsor will be registered.		

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Population:	Patients who diagnosed with hypertension based upon the most recent JSH guideline, and who comply with inclusion and exclusion criteria may qualify for participation in this study. (if applicable) <u>Inclusion criteria</u> - Patients who are prescribed with Micatrio® Combination Tablets by the discretion of investigators based on the Japanese package insert - Patients who have never been treated with Micatrio® Combination Tablets before enrolment <u>Exclusion criteria</u> - Patients who are participating/ planned to participate in a clinical trial. *Contraindication as per Japanese Package Insert should be respected.		
Variables:	Exposure to Micatrio® Combination Tablets is estimated as time from the day Micatrio® Combination Tablets is initiated until the day the drug is last administrated on a patient-level (or the final contact with last regular observation) and considering dosage. Outcomes: <u>Safety</u> Any suspected ADRs (primary outcome), Serious AEs, AEs for important identified risks and AEs for important potential risks <u>Effectiveness</u> Effectiveness will be assessed with a focus on the following variable as secondary outcome. - Change from the baseline in clinic diastolic blood pressure (DBP)[mmHg] at Week 52 - Change from the baseline in clinic systolic blood pressure (SBP)[mmHg] at Week 52 Others Demographics, Administration of Micatrio® Combination Tablets, adherence, Previous/Concomitant medications, Blood pressure, controlled hypertension, pulse rate and Laboratory tests		

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Data sources:	CRFs for individual patients will be gathered by the EDC system. After the medical examination and observation at the specified points (Baseline, Week 4, 8, 12, 24, 36 and 52 or discontinuation) are completed, the investigator needs to immediately enter data of the registered patients (including withdrawals and dropouts) in the EDC. Two case books will be used, data are to be transmitted immediately after being entered into EDC at Week 8 (Book 1) and Week 52 (Book 2) after the start of treatment or at discontinuation. In case that any adverse events occur, the data should be immediately entered into EDC and transmitted.		
Study size:	500		
Data analysis:	Due to the nature of the observational study, no confirmatory statistical testing is foreseen in this study. Analyses are descriptive in nature including means, standard deviation, min, Q1, medians, Q3, max, frequency and percentages.		
Milestones:	Start of data collection: 20 January 2017 End of data collection: 30 April 2019 (in plan) Interim report: After Week 8 data will be collected Final report of study results: 1Q 2020(in plan)		