Protocol Synopsis

Name of Sponsor: Korea Otsuka Pharmaceutical Co., Ltd. Name of Investigational Medicinal Product: Cilostazol (Pletaal® SR cap.)	Protocol# 021-KOA-1201n
Protocol Title:	A Prospective, Post Marketing Observational Study to evaluate the safety of Pletaal® SR capsule
Clinical Phase:	Post Marketing Observational Study
Treatment Indication:	1. Treatment of ischemic symptoms including ulceration, pain and coldness in chronic arterial occlusion (Berger's disease, arteriosclerosis obliterans, diabetic peripheral angiopathy). 2. Prevention of recurrence of cerebral infarction (excluding cardiogenic cerebral embolism).
Objective(s):	Pletaal® SR capsule(q.d.) is developed and approved as improving Pletaal® Tablet(b.i.d.). But there is no safety data of Pletaal® SR capsule. The objective of this study is to evaluate following items in relation with use of Pletaal® SR capsule in general medical practice; 1. Serious adverse event and adverse drug reaction profile 2. Unexpected adverse event/adverse drug reaction profile 3. Known adverse drug reaction profile 4. Adverse event of product abuse/misuse, drug interactions or overdose 5. Other information related to the product safety The hypothesis of this study is that Pletaal® SR capsule is safe in the treatment.

Trial Design & Method:	This is a Post Marketing Observational Study of cilostazol (Pletaal® SR capsule). This study will be conducted in a prospective, single-arm, multi-center format. As this study is observational in nature to collect the safety data after administrating the Pletaal SR capsule, from baseline to 16 weeks. The patient's follow-up is not prescriptive in nature and must be left up to the judgment of the physician (investigator), within the period of observation set forth in the protocol.
Trial Population:	At least 3000 patients will be enrolled for this study to collect the safety data among various groups. Investigators across the country will be participating in this study and the number of patients to be enrolled by each investigator will vary.

Inclusion/Exclusion Criteria:	**Inclusion Criteria** Patients must meet all of the following inclusion criteria to be eligible for enrollment into the study : 1. Patients who are prescribed Pletaal® SR capsule treatment as per investigator's medical judgment for adults aged 19 and over. 2. Patients who gave written authorization to use their personal and health data Physician (Investigator) will refer to the product market authorization (package insert) for inclusion criteria. **Exclusion Criteria** Patients presenting with any of the following will not be included in the study 1. Patients with hemorrhage 2. Patients with congestive heart failure 3. Patients with known hypersensitivity to Cilostazole or any ingredients of Pletaal® 4. Women who are pregnant or may possibly become pregnant 5. Patients who is not eligible to participate this study as investigator's medical judgment Physician (Investigator) will refer to the product market authorization (package insert) for exclusion criteria.
Investigational Medicinal Product(s), Dose, Dosage regimen, Treatment period, Formulation, Mode of Administration:	The usual adult dose of Pletaal® SR capsule is 200mg of cilostazol, once daily, by the oral route. This is taken in the fasting state, avoid eating.

Safety Measure:	1. The incidence rate and the number of AE/ADRs 2. The incidence rate of Tarchycardia and Palpitation after Pletaal® SR capsule administration 3. The number and percentage of drop-out patients according to AEs 4. The difference between AE and drug compliance according to patient's character

Statistical Methods:	1. Demographic Information & Baseline Characteristics Data for the baseline characteristics is demonstrated by descriptive statistics. Mean, standard deviation(SD), minimum value, median, maximum value for continuous variables and frequency(n), percentage(%) for categorical variables will be presented in overall patients. 2. Safety Analysis - The incidence rate and the number of AE/ADRs - The incidence rate of Tachycardia and Palpitation after Pletaal® SR capsule administration - The number and percentage of drop-out patients according to AEs - The difference between AE and drug compliance according to patient's character All adverse events (AEs) observed during/after the administration will be analyzed as safety assessment. The number of patients and the number of AE/ADR, SAE/Serious ADR (SADR), unexpected AE/ADR will be calculated (frequency and percentage). In the final report, the incidence rate of all AEs during the study period will be estimated with its 95% confidence interval. The number and percentage of drop-out patients according to AEs and the incidence rate of AEs for the severity will be estimated. Safety measures will be summarized and analyzed to find the risk factors in overall patients by background factors (baseline characteristic, drug administration, concomitant drug treatment etc.). The analysis will be performed using Chi-square test or Fisher's exact test. The number and percentage of AEs/ADRs will be summarized for special population (elderly patients, patients with liver or renal disease). Record the term of adverse event according to the System Organ Class, Preferred Term, Lower-Level Terms in the Medical Dictionary for Regulatory Activities (MedDRA). If there is no preferred term, look up the WHO Adverse Reactions Terminology (WHOART).

Estimated Duration of study	Planned study schedule is as below; 1. Study duration: Jan 2013 – Dec 2014 2. Submit the final reports to KFDA: within 1 year of study completion 3. Submit the CSR to global within one year after LPLV or end of data collection as defined in protocol or contract