4. ABSTRACT

Name of company: Boehringer Ingelheim			
Name of finished medicinal product: Spiolto Respimat 28 puffs/ Spiolto Respimat 60 puffs			
Name of active ingredient: Tiotropium + olodaterol fixed-dose combination solution for inhalation - RESPIMAT			
Protocol date: 15 November 2015	**Study number:** 1237.34	**Version/Revision:** Ver 2.0	**Version/Revision date:** 10 MAY 2016
Title of study:	Post Marketing Surveillance (PMS) on long-term use of tiotropium+olodaterol fixed dose combination (Tio+Olo FDC) 5µg /5µg in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) in Japan		
Rationale and background:	The number of patients exposed to Tio+Olo FDC 5µg /5µg is limited in clinical trials. In addition, the clinical trial setting had some limitations compared to the real-world setting, such as inclusion/exclusion criteria defined patient's background and restriction of concomitant medications. In addition it is important to understand treatment patterns in routine clinical practice.		
Research question and objectives:	The study objective is to assess the long-term safety and effectiveness of Tio+Olo FDC 5µg/5µg in patients with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) in real-world setting.		
Study design:	Observational study based on newly collected data for 52 weeks.		
Population:	- Inclusion criteria · Patients who have been diagnosed with chronic obstructive pulmonary disease (chronic bronchitis, emphysema) by physician and need to be treated co-administration of a long-acting inhalational anticholinergic and a long-acting inhalational β2-agonist to relief of various symptoms associated with the obstructive impairment of airways. · Patients who are prescribed Tio+Olo FDC 5µg /5µg for the first time - Exclusion criteria · Patients who have already been registered in this study once (re-entry of patients is not allowed) · Patients who are participating in a clinical trial or registry. · Patients who have a contraindication to Tio+Olo FDC 5µg /5µg		

	defined in the package insert for Tio+Olo FDC 5µg /5µg.
Variables:	Baseline characteristics Demographics Duration from indication COPD status (severity (i.e. GOLD stage)) Tio+Olo FDC 5µg /5µg administration status Medical history/ baseline conditions Previous /concomitant therapies Concomitant/ past medications (start/stop date, dosage, unknown) Chronic obstructive pulmonary disease (chronic bronchitis, emphysema) medications (ICS, LABA, LAMA, other, unknown) other medications (start/stop date, dosage, unknown) CAT (COPD Assessment Test) FVC and FEV_1 (if the data is available at sites with information of pulmonary medication (i.e. pre-dose or post-dose)) Pregnancy
Data sources:	Patients' data will be collected by electronic Case Report Form (eCRF) on EDC system
Study size:	1000 (safety set)
Data analysis:	Analyses are descriptive in nature. AEs are described with their incidence and incidence rate per treatment time. Subgroup analyses are performed for suitable sized samples with regard to patient characteristics and AE groups of medical interest. Due to the nature of the observational study, no confirmatory statistical testing is foreseen in this study.
Milestones:	Study Report planned to be archived in 3Q 2019 Study result based on study report is submitted in the re-examination document to PMDA in 4Q 2023.