Protocol Synopsis

Name of Sponsor: Korea Otsuka Pharmaceutical Co., Ltd. Name of Investigational Medicinal Product: Aripiprazole (Abilify® Tablets/Abilify® ODT)	Protocol# 031-KOA-1101n

Protocol Title:	Post-Marketing Surveillance of Safety and Efficacy of Abilify® Tablets/Abilify® ODT in Korean Patients with Tourette's Disorder under the "New Drug Re-Examination"
Clinical Phase:	Post Marketing Surveillance
Treatment Indication:	Pediatric patients 6 to 18 years of age with Tourette's Disorder according to the approved product market authorization(labeling)
Objective(s):	The objective of this surveillance is to evaluate following items in relation with use of Abilify® Tablets/Abilify® ODT in normal 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. Non-serious adverse drug reaction profile 5. Other information related to the product safety and efficacy The hypothesis of this study is that Abilify® Tablets/Abilify® ODT is safe and efficacious in the treatment of Korean patients with Tourette's Disorder.

Trial Design:	This is a Post-Marketing Surveillance study of Abilify® Tablets/Abilify® ODT in accordance with Korean regulations on New Drug Re-examination (i.e. New Drug Re-examination Standards: MFDS Notification). This study will be conducted in a prospective, single-arm, multi-center format. As this study is observational in nature, 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. The protocol will be developed in accordance with the MFDS guideline. *MFDS : Ministry of Food and Drug Safety
Trial Population:	At least 600 patients will be enrolled for surveillance to meet the local regulatory requirements. About 50~60 investigators across the country will be participating in this surveillance and the number of patients to be enrolled by each investigator will vary. Among the 600 enrolled patients, it is expected that at least 60 patients will enter the long-term surveillance (i.e. observation for at least 12 weeks).

Inclusion/Exclusion Criteria:	**Inclusion Criteria** 1. Pediatric patients 6 to 18 years of age with Tourette's Disorder 2. Patients who are prescribed Abilify® Tablets/Abilify® ODT treatment as per investigator's medical judgment. 3. Patients who gave written authorization to use their personal and health data 4. Patients starting Abilify® Tablets/Abilify® ODT treatment after agreement is in place Investigators will refer to the product market authorization (label) for inclusion criteria. **Exclusion Criteria** 1. Patients with known hypersensitivity to Aripiprazole or any excipients of Abilify® Tablets/Abilify® ODT 2. Patients who have been treated with Abilify® Tablets/Abilify® ODT 3. Patients with rare hereditary problems of galactose intolerance, the lapp lactase deficiency, or glucose-galactose malabsorption 4. Patients with score 0(Not assessed) or 1(Normal, not at all ill) in the TS-CGI-S 5. Patients participating in other clinical trial. Investigators will refer to the product market authorization (label) for exclusion criteria.
Investigational Medicinal Product(s), Dose, Dosage regimen, Treatment period, Formulation, Mode of Administration:	**Dose:** Aripiprazole (Abilify® Tablets 2mg, 5mg, 10mg, 15mg, Abilify® ODT 10mg, 15mg) **Dosage regimen:** Aripiprazole (Abilify® Tablets/Abilify® ODT) is being used 2mg/day to 20mg/day as per approved marketing authorization (labeling). **Mode of administration:** P.O

Safety Measures:	1. Adverse event collection 2. Others: vital signs (blood pressure and pulse), height, weight ,BMI
Efficacy Measures:	1) Main surveillance Mean change in the TS-CGI from baseline to next visit(at least 6 weeks interval from baseline) post-treatment 2) Long-term surveillance Mean change in the TS-CGI from baseline to next visit(at least 12 weeks interval from baseline) post-treatment

Statistical Methods:	Safety analysis set includes all subjects who received Abilify® Tablets/Abilify® ODT at least once and followed up for the safety evaluation. Efficacy analysis set includes all subjects who received Abilify® Tablets/Abilify® ODT for at least 6 weeks and efficacy evaluation data is available. For Long term surveillance, Efficacy analysis set includes all subjects who received Abilify® Tablets/Abilify® ODT for at least 12 weeks and efficacy evaluation data is available. In interim reports, the descriptive statistics for continuous variables and frequency (n) and percentage (%) for categorical variables will be presented in overall patients. In final report (Re-examination report), safety and efficacy measures will be summarized and analyzed in overall patients and by background factors as well as ADHD patients will analyzed separately. For continuous variables, the descriptive statistics will be presented, and the analysis will be performed using Paired t-test (in case of Secondary Efficacy Endpoint no.1, One sample t-test) or Wilcoxon signed rank test in overall patients and will be performed using Two sample t-test(or ANOVA) or Wilcoxon rank sum test(or Kruskal-Wallis test) between categories of background factors. For categorical variables, frequency (n) and percentage(%) will be presented, and the analysis will be performed using Chi-square test or Fisher's exact test between categories of background factors. Also, 95% confidence interval of incidence rate of adverse event will be described. Data for special population (i.e. pregnant women, elderly patients, patients with liver or renal disease) will be presented as well.

Estimated Duration of study	Planned study schedule as per local regulation is as below; 1. Estimated regulatory approval on Abilify® indication addition: November 2011 2. Estimated product relaunch date: February 2012 3. Study period: March 2012 – November 2015 4. DB reconciliation(clinical DB vs safety DB): periodically every 3 months and after completion of data collection before writing periodic report or reexamination report 5. Interim reports to MFDS: every 6 months for first 2 years, then annually thereafter. 6. Final report to MFDS: within 3 months of study completion

[Appendix]

Management and reporting of safety information

Procedures for the collection, management and reporting of individual cases of safety information while the study is being conducted, and for the periodic and end of study reconciliation of serious/non-serious adverse events between PV database and study database, aligned with the current version of G-SOP-ALL-007.

Definition of Safety information	Safety Information as below will be reported in accordance with the current Otsuka Global GxP/Pharmacovigilance Glossary. "Any information from any source containing information such as • Adverse event or suspicion thereof • Lack of efficacy • Overdose, abuse, misuse (even without resulting adverse reaction) • Medication error • Exposure during pregnancy or lactation (including uneventful) • Counterfeit product • Transfer of infectious disease by the medicinal product concerned • Product complaint report which includes medically important information • Pediatric use • Occupational exposure."