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Completion of Long-Term Phase 3 Safety Trial for Latuda® (lurasidone HCl)

Dainippon Sumitomo Pharma Co., Ltd. (DSP) announced today completion of a double-blind, long-term safety and tolerability study of Latuda® (lurasidone HCl) tablets for the treatment of patients with schizophrenia or schizoaffective disorder. In the 12-month study, once-daily LATUDA was found to be well-tolerated and consistent with previous evaluations of its safety and tolerability.

This double-blind trial assessed the safety and tolerability of LATUDA for up to 12 months with once-daily doses of LATUDA 40, 80 or 120 mg, or risperidone* 2, 4 or 6 mg, in clinically stable outpatients with chronic schizophrenia or schizoaffective disorder. Several safety and tolerability assessments including adverse events, body weight, prolactin, ECG and lipid parameters were evaluated in the study.

The most commonly reported adverse events for LATUDA (greater than 5% and at least twice the rate of placebo) include nausea (16.7%), akathisia (14.3%), somnolence (13.6%) and vomiting (10.0%). The most commonly reported adverse events for risperidone include weight increased (19.8%) and somnolence (17.8%), nausea (10.9%) and akathisia (7.9%). In the trial, the observed effect of LATUDA doses on mean weight changes from baseline were -0.9 kg compared to 2.6 kg for risperidone. Median change in metabolic parameters for the LATUDA group as compared to risperidone were: glucose -0.5 mg/dL vs. 3.0 mg/dL; triglycerides -3.5 mg/dL vs. -1.0 mg/dL; and prolactin levels 0.10 ng/mL vs. 9.10 ng/mL, respectively, at 12 months study endpoint/LOCF.

The safety sample consisted of 427 patients randomized to LATUDA and 202 patients randomized to risperidone (2:1 randomization). Of these patients, 147 (34 percent) completed 12 months of treatment in the LATUDA group and 89 (44 percent) in the risperidone group. Discontinuations due to adverse events and insufficient clinical response, respectively, occurred in 17 percent and 7 percent of patients in the LATUDA group, and 11 percent and 6 percent of patients in the risperidone group.

Full results of the study are planned for presentation at a scientific meeting later this year.

* *Risperidone is manufactured by Janssen.*

About LATUDA
LATUDA is an atypical antipsychotic indicated for the treatment of patients with schizophrenia. LATUDA was approved by the U.S. Food and Drug Administration on October 28, 2010 (U.S. time). The recommended starting dose of LATUDA is 40 mg once daily. LATUDA should be taken with food. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 40 mg/day to 120 mg/day. In the 6-week controlled trials, there was no suggestion of added benefit with the 120 mg/day dose, but there was a dose-related increase in certain adverse reactions. Therefore, the maximum recommended dose is 80 mg/day. Sunovion Pharmaceuticals Inc. a U.S. subsidiary of DSP, plans to launch LATUDA in early February, 2011.