LATUDA® (lurasidone HCl) SIGNIFICANTLY REDUCED SYMPTOMS OF SCHIZOPHRENIA IN NEW CLINICAL STUDY

Dainippon Sumitomo Pharma Co., Ltd. announced today positive preliminary findings from a LATUDA® (lurasidone HCl) clinical trial, PEARL 3. Both LATUDA doses studied were shown to be significantly more effective than placebo in treating symptoms of schizophrenia as measured by the primary and secondary efficacy endpoints, the Positive and Negative Syndrome Scale (PANSS) total score and the Clinical Global Impressions-Severity Scale (CGI-S), respectively. The safety findings observed in the trial were consistent with previous LATUDA clinical trials. Full results of PEARL 3 will be presented at a scientific meeting in December.

The PEARL 3 study (Program to Evaluate the Antipsychotic Response to Lurasidone) is part of an extensive worldwide schizophrenia clinical development program, involving approximately 2,900 subjects. The PEARL 3 study was a double-blind, placebo-controlled, 6-week clinical trial conducted in 64 sites worldwide involving 488 patients with schizophrenia. The study had three active treatment arms: one for each of the two fixed doses of LATUDA and one for the dose of quetiapine fumarate extended-release tablet*, that was included in the study as an active control arm that established assay sensitivity. The most common adverse events reported for the combined LATUDA group (greater than 5% and at least twice the rate of placebo) during the 6-week treatment period were: akathisia, nausea, parkinsonism, dizziness and somnolence.

About LATUDA® (lurasidone HCl)
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).

* quetiapine fumarate extended-release tablet is manufactured by AstraZeneca