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Dainippon Sumitomo Pharma announces Pan-Asia study results for lurasidone, an atypical antipsychotic agent, in the treatment of schizophrenia

Dainippon Sumitomo Pharma Co., Ltd. (DSP) (Headquarters: Osaka, Japan; President: Masayo Tada) announced the results of a Pan-Asia study, a placebo-controlled trial of lurasidone hydrochloride (generic name, "lurasidone") in the treatment of patients with schizophrenia.

The study was a double-blind, placebo-controlled, six-week clinical trial (with an established active comparator) which was conducted with schizophrenia patients in Japan, Korea and Taiwan. Subjects were randomized to four arms; placebo (129 subjects), lurasidone 40 mg/day (125 subjects), lurasidone 80 mg/day (129 subjects) and established active comparator (64 subjects). Efficacy of lurasidone was evaluated using the Positive and Negative Syndrome Scale (PANSS) total score as the primary endpoint and the Clinical Global Impressions Severity scale (CGI-S) as the secondary endpoint.

Lurasidone did not demonstrate a statistically significant improvement vs placebo in PANSS total score change at the 6-week study endpoint, despite a significant within group reduction of the total PANSS score after treatment with lurasidone at 40 mg/day and 80 mg/day. This clinical trial is viewed as a failed study, as it was unsuccessful in establishing assay sensitivity.

With respect to safety, more than 40 clinical trials involving greater than 2,500 patients treated with lurasidone have been conducted to date. The most commonly observed adverse events for lurasidone 40mg/day and 80mg/day in the study were comparable to the collective results from these overseas clinical studies.

"While the results of this study were unexpected for lurasidone, based on our prior clinical experience with the product we remain highly confident in our development plan for lurasidone in Japan," said Masayo Tada, president and chief executive officer, Dainippon Sumitomo Pharma Co., Ltd. "Building upon the clinical success and approval of lurasidone in the United States, we believe we obtained useful data as a result of conducting the trial that will assist us with the design of future studies to support the registration of lurasidone in Japan."

Submission of an application for approval to the Japanese Ministry of Health, Labour & Welfare based on these results is not possible at this point in time. Therefore, a new Phase III study for lurasidone is planned to support this registration.