



DAINIPPON SUMITOMO PHARMA ANNOUNCES LURASIDONE PHASE III DATA IN PATIENTS WITH SCHIZOPHRENIA

*– The company plans to submit a New Drug Application (NDA) to the
U.S. Food and Drug Administration in 2010 –*

San Francisco, Calif., May 20, 2009 – Dainippon Sumitomo Pharma Co., Ltd., (DSP) announced today positive results from the first phase 3 clinical trial for lurasidone, which is under clinical development globally, for the treatment of patients with schizophrenia. In this six-week, double-blind, placebo-controlled trial, lurasidone 80 mg/day was significantly more effective than placebo for the treatment of acute schizophrenia. In addition, lurasidone was well-tolerated and had a relatively low discontinuation rate. The findings were presented at the 162nd Annual Meeting of the American Psychiatric Association in San Francisco, held on May 16-21.

PEARL 1 (Program to Evaluate the Antipsychotic Response to Lurasidone) is part of an extensive worldwide phase 3 clinical development program, involving more than 2,000 patients, intended to evaluate the safety and efficacy of lurasidone for the treatment of schizophrenia. In addition to the primary finding that lurasidone 80 mg/day was significantly more effective than placebo at the study endpoint, lurasidone was associated with greater improvement on both the Positive and Negative Syndrome Scale (PANSS) total score (primary endpoint) and the Clinical Global Impressions Severity scale (CGI-S, key secondary endpoint) at all visits between weeks two and six. PEARL 1 also evaluated two other fixed doses of lurasidone, 40 mg/day and 120 mg/day, which did not demonstrate separation from placebo on the PANSS or CGI-S at study endpoint.

“People with schizophrenia need new treatment options that offer a combination of efficacy, safety and tolerability so that the symptoms can be stabilized and effectively treated,” said Henry Nasrallah, M.D., professor of psychiatry and neuroscience and director of the schizophrenia research program at the University of Cincinnati College of Medicine. “Lurasidone has the potential to be an important new therapeutic option for patients with schizophrenia.”

Lurasidone’s effect on weight was similar to placebo (median change 0.3 kg for overall lurasidone group vs. 0 kg for placebo) as was its effect on lipid and glucose measures. Lurasidone was also well tolerated with a lower overall discontinuation rate (31%) compared to placebo (43%) and few adverse event-related discontinuations (6% and 2% for the overall lurasidone group and placebo, respectively).

Adverse events seen in the trial were generally mild. The most commonly reported adverse events for lurasidone (greater than 5% and at least twice the rate of placebo) were akathisia (17.6% vs. 3.1% placebo), somnolence (11.7% vs. 5.5%), parkinsonism (6.8% vs. 0), and increased weight (5.1% vs. 2.4%).

“DSP is committed to the development of lurasidone and we look forward to the completion of our phase 3 clinical trial program and submission of a new drug application to the U.S. FDA,” said Masayo Tada, president and chief executive officer, Dainippon Sumitomo Pharma Co., Ltd. “More importantly, we believe that lurasidone will be a valuable new treatment option for patients and physicians in addressing currently unmet needs in the treatment of schizophrenia.”

“The development program for lurasidone is intended to establish efficacy for the core symptoms of schizophrenia, characterize its safety profile and explore its effects in the treatment of cognitive impairment and other areas not adequately addressed by current therapies,” said Antony Loebel, M.D., vice president of clinical research, Dainippon Sumitomo Pharma America, Inc. “As a large, global trial, the PEARL 1 study is an important new addition to the existing clinical trial database.”

PEARL 1 Study Design

This randomized, placebo-controlled, double-blind, multinational clinical trial evaluated the efficacy and safety of lurasidone 40 mg, 80 mg and 120 mg once daily compared to placebo, over six weeks in patients with acute schizophrenia. Patients were diagnosed with schizophrenia (using DSM-IV criteria) and were required to have an acute exacerbation of psychotic symptoms with a PANSS total score of 80 or higher at study baseline.

A total of 500 patients were randomized equally to the four treatment arms. The pre-specified primary endpoint was change from baseline in the PANSS total score over the six-week study duration for each lurasidone dose group vs. placebo. A key secondary endpoint was the change from baseline in CGI-S over the six-week study period. Efficacy data were statistically analyzed using a mixed model for repeated measures. Multiple safety assessments were done, including vital signs, weight, ECGs, movement disorder scales (SAS, BAS, AIMS), and laboratory assessments.

The study was conducted at 51 sites worldwide. Twenty-two sites in the United States randomized 278 patients, 21 sites in Europe randomized 148 patients and eight sites in Asia randomized 48 patients. The majority of trial participants were male with a mean age of 39 years. The mean time since initial diagnosis was approximately 14 years, and patients had, on average, four or more hospitalizations prior to study entry.

U.S. Placebo-Controlled Study Findings

Lurasidone has been studied in three double-blind, placebo-controlled, six-week trials involving more than 650 patients with schizophrenia, of which 392 patients received lurasidone. Two of the three studies demonstrated that lurasidone had superior efficacy compared to placebo at doses ranging between 40 mg and 120 mg/day. A third study, which examined three fixed doses of lurasidone (20 mg, 40 mg, and 80 mg/day) did not show statistical differences vs. placebo. This trial is regarded as “failed,” or inconclusive, as haloperidol (10 mg/day), which was included for purposes of assay sensitivity, also failed to distinguish from placebo.

These data showed that lurasidone was well tolerated with a low propensity for EPS, QTc interval changes and weight, lipid and glucose adverse effects. Adverse events seen in the three trials were generally mild. The most common adverse events reported at a frequency of at least 5% and at least twice the rate of placebo among the combined lurasidone doses in these trials were akathisia (11.6% vs. 4.7% placebo), somnolence (14.3% vs. 7.1%) and nausea (14.8% vs. 6.1%).

About Lurasidone

Discovered and developed by Dainippon Sumitomo Pharma Co., Ltd., lurasidone is a novel compound with a unique receptor-binding profile including high affinity for dopamine D₂, serotonin 5-HT_{2A}, 5-HT₇, 5-HT_{1A}, and noradrenalin α_2c receptors. Lurasidone has low affinity for histamine H₁, and cholinergic M₁ receptors.

About Schizophrenia

Schizophrenia is a chronic, disabling and serious medical illness that affects between two to three million American adults and more than 24 million adults worldwide. Schizophrenia affects men and women equally and occurs at similar rates in all ethnic groups around the world. Schizophrenia is a treatable medical condition and is thought to be caused by a combination of environmental and genetic factors. The condition is characterized by positive and negative symptoms, such as hallucinations, delusions, disorganized thinking, lack of emotion, lack of energy, as well as cognitive impairments including problems with memory, attention and the ability to plan, organize and make decisions. In 2002, the overall cost of schizophrenia in the United States was estimated to be \$62.7 billion, with \$22.7 billion in direct health care costs.

About Dainippon Sumitomo Pharma

Dainippon Sumitomo Pharma Co., Ltd., (DSP), is a top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical, animal health and food and specialty products. DSP's strong research and development presence in the areas of CNS, diabetes, cardiovascular disease, and inflammation/allergy, is based on the merger in 2005 between Sumitomo Pharmaceuticals Co., Ltd., and Dainippon Pharmaceutical Co., Ltd. With global expansion plans on the horizon, this multi-billion dollar company has about 5,000 employees worldwide. Through its research and development efforts, DSP aims to extend our experience, commitment and vision worldwide. Located in Fort Lee, NJ, Dainippon Sumitomo Pharma America, Inc. is a subsidiary of DSP.

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