



## **LURASIDONE DEMONSTRATED EFFICACY IN TREATING PATIENTS WITH SCHIZOPHRENIA IN PIVOTAL PHASE 3 STUDY**

*Lurasidone Met Primary and Key Secondary Efficacy Endpoints at Both 40 and 120 mg/day; Weight and Metabolic Profile Similar to Placebo*

**Osaka, Japan / Fort Lee, N.J., August 26, 2009** – Dainippon Sumitomo Pharma Co., Ltd., (DSP) announced today positive results from **PEARL 2** - a phase 3 clinical trial of lurasidone for the treatment of patients with schizophrenia. In this trial, both lurasidone 40 and 120 mg/day were significantly more effective than placebo for the treatment of schizophrenia. Lurasidone was well-tolerated with an overall discontinuation rate that was similar to placebo.

*“We are pleased with the results of this study as these data reinforce our belief that lurasidone will be an important treatment option for patients with schizophrenia,” said Masayo Tada, president and chief executive officer, Dainippon Sumitomo Pharma Co., Ltd. “We plan to submit our NDA filing package for lurasidone to the U.S. FDA in early 2010.”*

**PEARL 2** (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. The **PEARL 2** study was a double-blind, fixed-dose, placebo-controlled clinical trial involving 478 inpatients with acute schizophrenia that were randomized to receive either lurasidone 40 or 120 mg/day, olanzapine 15 mg/day or placebo for six weeks. The active comparator, olanzapine, was used for purposes of establishing assay sensitivity.

Lurasidone 40 and 120 mg, taken once-daily, demonstrated significantly greater improvement versus placebo on the primary efficacy measure, the Positive and Negative Syndrome Scale (PANSS) total score, at study endpoint. PANSS score changes from baseline for lurasidone 40 and 120 mg/day versus placebo were -25.7 and -23.6 vs. -16.0, respectively, at study endpoint. A total of 53% of patients on lurasidone 40 mg/day and 47% of patients on lurasidone 120 mg/day demonstrated a 30% or more improvement on the PANSS total score from baseline versus 38% on placebo.

In addition, both lurasidone dose groups were significantly more effective than placebo on the Clinical Global Impressions Severity scale (CGI-S), the key secondary efficacy endpoint. The CGI-S score changes from baseline for lurasidone 40 and 120 mg/day versus placebo were -1.5 and -1.4 vs. -1.1, respectively, at study endpoint.

*“Patients with schizophrenia and their health care providers are in need of new treatment options that provide consistent efficacy with a lower impact on weight, lipids, and movement disorders”, said Herbert Meltzer, M.D., a study investigator and professor of psychiatry and pharmacology at the Vanderbilt University School of Medicine. “Lurasidone appears to be a potentially significant new treatment option for schizophrenia.”*

The effect of lurasidone on weight was similar to placebo [median weight change: 0.9 kg (2 lbs) for 40 mg/day, 0.5 kg (1.1lbs) for 120 mg/day vs. 0 kg for placebo at study endpoint]. The incidence of clinically significant weight gain ( $\geq 7\%$  increase from baseline to study endpoint) was 7.6% for lurasidone 40 mg/day, 4.2% for lurasidone 120 mg/day and 7.0% for placebo.

Changes in total cholesterol and other lipid measurements for both lurasidone doses (40 and 120 mg/day) were similar to placebo (median change: total cholesterol -8.0 mg/dL and -5.0 mg/dL vs. -5.0 mg/dL placebo; and triglycerides -3.0 mg/dL and 4.5 mg/dL vs. -1.0 mg/dL placebo, respectively, at study endpoint).

*“PEARL 2 data are consistent with previous lurasidone placebo-controlled studies and underscore the potential of lurasidone to effectively treat patients with schizophrenia,” said Antony Loebel, M.D., vice president of clinical research, Dainippon Sumitomo Pharma America, Inc.*

Lurasidone was also well-tolerated with an overall discontinuation rate similar to placebo (40% vs. 39% placebo) and few adverse event-related discontinuations (9% for both the overall lurasidone group and placebo). Adverse events seen in the trial were generally mild. The most commonly reported adverse events for lurasidone 40 and 120 mg/day combined (greater than 5% and at least twice the rate of placebo) were akathisia (17.3% vs. 0.9% placebo), somnolence (12.2% vs. 4.3% placebo), sedation (11.4% vs. 3.4% placebo), parkinsonism (10.1% vs. 1.7% placebo), nausea (9.3% vs. 4.3% placebo), and dystonia (5.5% vs. 0.9% placebo).

Olanzapine 15 mg/day produced significantly greater improvements than placebo on both the PANSS total score (-28.7 vs. -16.0 placebo) and CGI-S (-1.5 vs. -1.1 placebo). A total of 64% of patients on olanzapine demonstrated a 30% or more improvement on the PANSS total score from baseline versus 38% on placebo. Patients on olanzapine reported a 3.1 kg (6.8 lbs) increase in median weight gain at study endpoint. The incidence of clinically significant weight gain ( $\geq 7\%$  increase from baseline to study endpoint) for olanzapine was 34.4% vs. 7.0% placebo. Olanzapine-treated patients had a greater increase in lipid parameters versus placebo (median change: total cholesterol 9.0 mg/dL vs. -5.0 mg/dL placebo; and triglycerides 24.0 mg/dL vs. -1.0 mg/dL placebo at study endpoint). The most commonly reported adverse events for olanzapine (greater than 5% and at least twice the rate of placebo) were increased weight (20.5% vs. 5.2% placebo), sedation (13.9% vs. 3.4% placebo), dry mouth (9.8% vs. 0.9% placebo), somnolence (9.0% vs. 4.3% placebo) and akathisia (7.4% vs. 0.9% placebo).

The company has submitted the results of the trial for presentation at a scientific meeting at the end of this year.

### **PEARL 2 Study Overview**

This randomized, fixed-dose, placebo-controlled, double-blind, multinational clinical trial was conducted at 52 sites worldwide primarily in hospital settings. Twenty-five sites in the United States randomized 286 patients, 18 sites in Asia randomized 115 patients, five sites in South America randomized 48 patients and four sites in Europe randomized 29 patients.

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. Trial participants had a mean age of 37.7 years with an average PANSS score of 96.6 at baseline. Patients had been diagnosed with schizophrenia, on average, for more than 13 years and most had been previously hospitalized prior to entering the study. Multiple safety assessments were done, including vital signs, weight, ECGs, movement disorder scales (SAS, BAS, AIMS), and laboratory assessments.

### **About Lurasidone**

Lurasidone is an atypical antipsychotic discovered and developed by DSP with a unique chemical structure. Lurasidone has high affinities for dopamine D<sub>2</sub>, serotonin 5-HT<sub>7</sub>, 5-HT<sub>2A</sub>, 5-HT<sub>1A</sub>, and noradrenalin α<sub>2C</sub> receptors and minimal-to-no affinity for histamine H<sub>1</sub> or cholinergic M<sub>1</sub> 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 its experience, commitment and vision worldwide. Located in Fort Lee, NJ, Dainippon Sumitomo Pharma America, Inc. is a subsidiary of DSP.

\*Olanzapine is manufactured by Eli Lilly.

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