



## STUDY DEMONSTRATING LURASIDONE IS EFFECTIVE IN PATIENTS WITH SCHIZOPHRENIA PUBLISHED IN THE JOURNAL OF CLINICAL PSYCHIATRY

*- Improvement Was Noted At Day 3 And All Subsequent Study Visits -*

**Fort Lee, N.J., June 3, 2009** – Dainippon Sumitomo Pharma Co., Ltd., (DSP) announced today that positive results from a phase 2 clinical trial for lurasidone in the treatment of patients with schizophrenia have been published in *The Journal of Clinical Psychiatry*. This six-week, randomized, double-blind, multicenter, placebo-controlled trial, involving 180 patients with acute schizophrenia, evaluated a single fixed dose of lurasidone 80 mg/day versus placebo. Lurasidone 80 mg/day produced statistically significant improvement versus placebo in both primary and secondary efficacy assessments at all study visits starting at day 3. In addition, lurasidone was generally well-tolerated and was associated with weight and metabolic changes that were similar to placebo. The study is available at [www.psychiatrist.com](http://www.psychiatrist.com).

“We are pleased to see the first publication reporting results of a lurasidone placebo-controlled trial in the treatment of patients with acute schizophrenia,” said Antony Loebel, M.D., senior author and vice president of clinical research, Dainippon Sumitomo Pharma America, Inc. “Findings from this phase 2 study are consistent with data emerging from the lurasidone global development program, including a recently completed, large phase 3 placebo-controlled trial.”

The primary efficacy measure was the BPRSd (Brief Psychiatric Rating Scale-derived). Lurasidone demonstrated significant improvement at Week 6 (LOCF endpoint) compared to placebo on the BPRSd (-8.9 vs. -4.2;  $p=0.012$ ), as well as on all secondary efficacy measures, including the PANSS (Positive and Negative Syndrome Scale) total score (-14.1 vs. -5.5;  $p=0.004$ ), PANSS positive subscale (-4.3 vs. -1.7;  $p=0.006$ ), PANSS negative subscale (-2.9 vs. -1.3;  $p=0.025$ ) and CGI-S (Clinical Global Impressions-Severity of Illness scale) (-0.6 vs. -0.2;  $p=0.007$ ) scores.

Lurasidone significantly improved depressive symptoms associated with schizophrenia, as measured by the Montgomery-Asberg Depression Rating Scale (MADRS) at the study endpoint. The mean changes in MADRS score were -2.9 vs. -0.1 ( $p=0.019$ ) for lurasidone and placebo, respectively.

Lurasidone’s effect on weight (median change 0.9 kg for lurasidone vs. 0.5 kg for placebo), lipids, and glucose was similar to placebo. No clinically important differences were observed between lurasidone and placebo for EPS (assessed using the Simpson-Angus Scale) or symptoms of tardive dyskinesia (assessed using the Abnormal Involuntary Movements Scale). There was a modest but significant worsening at endpoint in akathisia symptoms (assessed using the Barnes Akathisia Scale) for lurasidone versus placebo.

Lurasidone was well-tolerated with generally mild adverse events reported during the trial. The most commonly reported adverse events (reported frequency  $\geq 10\%$  among lurasidone subjects) for lurasidone versus placebo were nausea (16% vs. 3%), headache (11.1% vs 10%), constipation (11.1% vs 5.6%), vomiting (11.1% vs 5.6%), dyspepsia (11.1% vs 3.3%), somnolence (11.1% vs

3.3%), insomnia (10.0% vs 3.3%) and sedation (10.0% vs 4.4%). Lurasidone had a lower overall discontinuation rate (42.2%) compared to placebo (48.8%) with few adverse-event related discontinuations (6.7% and 1.1% for lurasidone and placebo, respectively).

### **Study Design**

This randomized, placebo-controlled, double-blind, multicenter clinical trial conducted in the U.S. evaluated the efficacy of lurasidone 80 mg once daily compared to placebo over six weeks in patients hospitalized for an acute exacerbation of schizophrenia (diagnosed using DSM-IV criteria). A total of 180 patients were randomized equally to the two treatment arms. Patients remained in the hospital until the day 28 assessment, after which patients could be discharged or remain hospitalized. The primary efficacy measure was the BPRSd extracted from the PANSS. The secondary efficacy measures included the PANSS total and positive, negative, general psychopathology, and cognitive subscales; the CGI-S, and the MADRS.

### **About Lurasidone**

Lurasidone is a novel compound synthesized and developed by Dainippon Sumitomo Pharma Co., Ltd. (DSP), as a potential psychotropic agent for the treatment of schizophrenia. Lurasidone has a unique chemical structure that differs from conventional and atypical antipsychotic agents. It possesses 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 noradrenaline α<sub>2C</sub> receptors. Lurasidone exhibits little or no affinity for histamine H<sub>1</sub> or acetylcholine 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. It 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 multi-billion dollar, 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. Today, DSP has about 5,000 employees with operations worldwide. Located in Fort Lee, NJ, Dainippon Sumitomo Pharma America, Inc. is a subsidiary of DSP.

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