Dainippon Sumitomo Pharma America Announces the NDA Submission of Lurasidone to the FDA for the Treatment of Schizophrenia

Fort Lee, N.J., January 4, 2010 – Dainippon Sumitomo Pharma America, Inc. (DSPA), a U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd. (DSP), submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for lurasidone, an investigational atypical antipsychotic agent for the treatment of schizophrenia. The application, submitted on December 30, 2009, includes data from more than 40 clinical studies involving more than 2,500 lurasidone-treated patients.

"This NDA marks a significant milestone for our company as we accelerated the global clinical development of lurasidone and achieved an earlier than anticipated submission to the FDA," said Masayo Tada, president and chief executive officer, Dainippon Sumitomo Pharma Co., Ltd. "We believe lurasidone will be a valuable new option for patients, their families and physicians for the treatment of schizophrenia."

The efficacy of once-daily lurasidone was demonstrated in four six-week, placebo-controlled studies, involving hospitalized patients with schizophrenia. These studies included the global PEARL 1 and PEARL 2 clinical trials (**P**rogram to **E**valuate the **A**ntipsychotic **R**esponse to **L**urasidone). Clinical trials demonstrated that lurasidone was generally well-tolerated with limited weight gain or changes in metabolic parameters. Furthermore, lurasidone was associated with mild changes in movement disorder parameters and prolactin levels.

"Lurasidone may offer physicians a new, once-daily treatment option for schizophrenia, where many unmet needs remain," said Antony Loebel, M.D., vice president of clinical development, DSPA. "We believe lurasidone has the potential to treat the symptoms of schizophrenia, while limiting troublesome side effects, such as weight gain and related metabolic risks."

About Lurasidone

Lurasidone is an atypical antipsychotic with a unique chemical structure that was discovered and developed by DSP. Lurasidone has high affinities for dopamine D_2, serotonin 5-HT_7, 5-HT_{2A}, 5-HT_{1A}, and noradrenaline α_{2C} receptors and minimal-to-no affinity for histamine H_1 or cholinergic M_1 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 America
Dainippon Sumitomo Pharma America, Inc. located in Fort Lee, N.J., is a subsidiary of Dainippon Sumitomo Pharma Co., Ltd. DSP is a multi-billion dollar, top-ten listed pharmaceutical company in Japan with more than 7,000 employees worldwide. DSP has a diverse portfolio of pharmaceutical, animal health and food and specialty products and strong research and development presence in the areas of CNS, diabetes, cardiovascular disease, and inflammation/ allergy. In October 2009, Sepracor Inc., based in Marlborough, MA, became a subsidiary of DSP.

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