Dainippon Sumitomo Pharma Co., Ltd.
Dainippon Sumitomo Pharma America, Inc

Dainippon Sumitomo Pharma America Announces FDA Acceptance of Lurasidone New Drug Application for Treatment of Schizophrenia

-The NDA Included More Than 40 Clinical Studies in Schizophrenia, Involving 2,500 Patients Treated with Lurasidone -

Fort Lee, N.J., March 10 – Dainippon Sumitomo Pharma America, Inc. (DSPA), a U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd. (DSP), today announced that the U.S. Food and Drug Administration (FDA) recently accepted for review the lurasidone New Drug Application (NDA) for the treatment of patients with acute schizophrenia. The NDA was submitted to FDA on December 30, 2009 and will receive a standard review.

"We are pleased that the lurasidone NDA has been accepted for review by the FDA," said Masayo Tada, president and chief executive officer, Dainippon Sumitomo Pharma Co., Ltd. "We look forward to the potential lurasidone may bring as it represents our commitment to developing therapies that provide clear value to patients and health care professionals."

The lurasidone NDA includes data from more than 40 clinical studies involving more than 2,500 lurasidone-treated patients. The efficacy and safety of lurasidone were evaluated in five six-week, placebo-controlled studies, involving hospitalized patients with schizophrenia. In four of these studies, lurasidone demonstrated significantly greater improvement versus placebo on the primary efficacy measure, the Positive and Negative Syndrome Scale (PANSS) total score, at study endpoint. In all five studies, lurasidone was well-tolerated and associated with limited weight gain or changes in metabolic parameters. In addition, patients treated with lurasidone exhibited mild changes in movement disorder parameters and prolactin levels.

Lurasidone is an atypical antipsychotic agent with a unique chemical structure. Lurasidone has high affinity for dopamine D_2, serotonin 5-HT_{2A} and serotonin $5HT_7$ receptors where it has antagonist effects. In addition lurasidone is a partial agonist at the serotonin $5HT_{1A}$ receptor. It has no appreciable affinity for histamine or muscarinic 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, Inc.
Dainippon Sumitomo Pharma America, Inc. (DSPA) located in Fort Lee, N.J., is a subsidiary of Dainippon Sumitomo Pharma Co., Ltd. (DSP). On April 1, 2010, DSP's two North American operations – DSPA and Sepracor Inc. – will merge, with Sepracor Inc. surviving as the company's U.S. headquarters and the Fort Lee location will remain a satellite office.

About Sepracor Inc.
Sepracor Inc., an indirect, wholly owned subsidiary of DSP, is a research-based pharmaceutical company dedicated to treating and preventing human disease by discovering, developing and commercializing innovative pharmaceutical products that are directed toward serving large and growing markets and unmet medical needs.

Sepracor's drug development program has yielded a portfolio of pharmaceutical products and candidates with a focus on respiratory and central nervous system disorders. Currently marketed products include LUNESTA® brand eszopiclone, XOPENEX® brand levalbuterol HCl Inhalation Solution, XOPENEX HFA® brand levalbuterol tartrate Inhalation Aerosol, BROVANA® brand arformoterol tartrate Inhalation Solution, OMNARIS® brand ciclesonide Nasal Spray and ALVESCO® brand ciclesonide HFA Inhalation Aerosol. Sepracor's corporate headquarters are located in Marlborough, Massachusetts. For more information, please visit Sepracor's website at www.sepracor.com.

About 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 more than 7,000 employees worldwide. Additional information about DSP is available through its corporate website at www.ds-pharma.co.jp .

Contact:
Julissa Viana
Dainippon Sumitomo Pharma America, Inc.
Email: media@dsp-a.com
Office: (201) 228-8356
Cell: (201) 850-9220