Sunovion and Takeda Announce Results from a New Study Showing Maintenance Treatment with Lurasidone Reduced the Risk of Relapse in Adults with Schizophrenia

Study Findings Presented at the 22nd European Congress of Psychiatry (EPA 2014) in Munich

Munich, Germany, 3 March 2014 – Sunovion Pharmaceuticals Inc. (“Sunovion”) (Head Office: Marlborough, Massachusetts) and Takeda Pharmaceutical International GmbH (“Takeda”) (Zurich, Switzerland) today announced the results from a double-blind, placebo-controlled study that evaluated the efficacy, safety and tolerability of lurasidone for the maintenance treatment of adults with schizophrenia. Lurasidone is a once-daily oral atypical antipsychotic indicated for the treatment of adults with schizophrenia and is currently available in the United States, Canada and Switzerland. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a Positive Opinion for lurasidone for the treatment of schizophrenia in adults on January 23, 2014.

In the double-blind, placebo-controlled, randomized withdrawal study, adult patients with schizophrenia who were stabilized on lurasidone (40-80 mg/day, flexibly dosed) during open-label treatment were randomized to either continued treatment with lurasidone (40 mg/day or 80 mg/day, flexibly dosed) or placebo for up to 28 weeks.¹ The primary endpoint was time to relapse over 28 weeks of the double-blind phase. The study showed that patients who received lurasidone (N=144) experienced a significant delay in time to relapse compared to patients who received placebo (N=141) (p=0.039).¹ Treatment with lurasidone was associated with a 33.7% reduction in risk of relapse vs. placebo (hazard ratio 0.663, 95% CI [0.447, 0.983]; p=0.041).¹

The study demonstrated that lurasidone was generally well-tolerated and had low rates of weight increase, as well as lipid and glucose effects.¹ It is important to minimize the adverse effects on long-term physical health of schizophrenia as patients are likely to remain on therapy for many years.

The discontinuation rate due to adverse events during the double-blind phase in patients treated with lurasidone was 13.9% vs. 15.6% for placebo.² In patients who completed the open-label stabilization phase (12 to 24 weeks) and were randomized to continued treatment with lurasidone
in the double-blind phase (up to 28 weeks), the most common treatment-emergent adverse events (incidence >10%) were akathisia (16.7%), insomnia (12.5%), headache (11.8%), nausea (11.1%) and anxiety (11.1%).

“Schizophrenia is a chronic condition that is severe and disabling, so it is important that healthcare providers not only address the acute symptoms of the illness, but also minimize the risk of experiencing relapse, a common challenge with the disorder,” said Rajiv Tandon, M.D., Vice Chair and Professor of Psychiatry at the University of Florida College of Medicine, Chief of Psychiatry at the North Florida/South Georgia Veterans Health System, Florida, United States and lead author on the study. “This study supports the efficacy of lurasidone in preventing relapse while producing few changes in weight, lipids and measures of glycemic control.”

These data were submitted to the EMA for potential inclusion in the Summary of Product Characteristics. These study results will also be submitted to relevant Health Authorities for review and potential inclusion in the respective prescribing information.

“Lurasidone has demonstrated efficacy and safety in a number of short-term studies of adults with schizophrenia,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer at Sunovion Pharmaceuticals Inc. “We are pleased to see the results of this study confirm the long-term efficacy of lurasidone in schizophrenia. In addition, long-term effects on metabolic parameters were consistent with the findings of short-term studies.”

About Schizophrenia
Schizophrenia is a chronic, serious and often severely disabling brain disorder that affects approximately 24 million people worldwide. Schizophrenia is characterized by symptoms such as hallucinations, delusions, disorganized thinking, lack of emotion and lack of energy, as well as problems with memory, attention and the ability to plan, organize and make decisions. Patients with schizophrenia have a life span that is decreased by approximately 10–22.5 years compared with the general population.

Direct and indirect costs associated with caring for patients with schizophrenia are considerable and can include utilization of other health services, pharmacotherapy, community care, supportive therapy, informal care and private expenditures, and patient and caregiver lost productivity. Hospitalization associated with patient relapse can significantly increase costs associated with disease management in schizophrenia.

Antipsychotics are considered to be the cornerstone of treatment for patients with schizophrenia, with agents generally classified as typical or atypical. Atypical agents are broadly considered to have safety and tolerability benefits over typical agents. Long-term and maintenance treatment of schizophrenia remains challenging due to multiple problems related to compliance, efficacy, safety and tolerability, which vary among different medications.
About Lurasidone
Lurasidone is an atypical antipsychotic developed originally by Dainippon Sumitomo Pharma Co., Ltd. The efficacy of lurasidone may be mediated through a combination of central dopamine Type 2 (D₂) and serotonin Type 2 (5HT₂A) receptor antagonism.

Lurasidone, marketed as Latuda®, is approved for the treatment of schizophrenia in the United States, Canada and Switzerland.


A marketing application has been filed for lurasidone with the Australian Therapeutic Goods Administration and the Taiwan Food and Drug Administration.

About Sunovion Pharmaceuticals Inc. (Sunovion)
Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercializing therapeutic products that advance the science of medicine in the Psychiatry, Neurology and Respiratory disease areas and improve the lives of patients and their families. Sunovion’s drug development program, together with its corporate development and licensing efforts, has yielded a portfolio of pharmaceutical products including Latuda® (lurasidone HCl) tablets, Lunesta® (eszopiclone) tablets, Xopenex® (levalbuterol HCl) inhalation solution, Xopenex HFA® (levalbuterol tartrate) inhalation aerosol, (arformoterol tartrate) inhalation solution, Omnaris® (ciclesonide) nasal spray, Zetonna® (ciclesonide) nasal aerosol and Alvesco® (ciclesonide) inhalation aerosol.

Sunovion is an indirect, wholly-owned U.S. subsidiary of Dainippon Sumitomo Pharma Co., Ltd. In March 2011, Dainippon Sumitomo Pharma Co., Ltd. and Takeda signed a Development and Commercialization Agreement of the oral formulation of lurasidone hydrochloride for the joint development and exclusive commercialization by Takeda in the 26 member states of the European Union at that time (excluding the United Kingdom), Switzerland, Norway, Turkey and Russia. Upon approval, Sunovion Pharmaceuticals Europe Ltd. will commercialize lurasidone in the United Kingdom.


About Takeda Pharmaceutical International GmbH
Takeda Pharmaceuticals International GmbH, headquartered in Zurich, is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited. As the largest pharmaceutical company in Japan and a leader in the global industry, Takeda’s mission is to strive toward better health for patients worldwide through leading innovation in medicine. It has a commercial presence covering more than 70 countries, with particular strength in Asia, North America, Europe and fast-growing emerging markets including Latin America, Russia-CIS and China. Takeda is ranked 12th by global Rx sales, 14th in the BRIC countries and 18th in Europe. Takeda’s commercial presence mainly covers the therapeutic areas of metabolic diseases, gastroenterology, oncology,

For a copy of this release, visit Sunovion’s web site at www.sunovion.com

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References
2. Sunovion data on file
7. Laursen TM. Life expectancy among persons with schizophrenia or bipolar affective disorder. Schizophr Res 2011;131:101–4