FOR MEDICAL MEDIA

New Post-Hoc Analyses Extend Understanding of the Efficacy and Safety of Lurasidone in the Treatment of Schizophrenia

Vienna, 31 March, 2015: Takeda Pharmaceuticals International GmbH (“Takeda”) and Sunovion Pharmaceuticals Inc. (“Sunovion”) today announced the results from three post-hoc analyses evaluating the efficacy and safety of Latuda® (lurasidone) in patients with schizophrenia at the 23rd European Congress of Psychiatry (EPA). The analyses suggest that lurasidone is associated with reduced hostility in patients with schizophrenia and reduced frequency of certain adverse events commonly associated with antipsychotic treatment.1,2,3 Latuda was granted Marketing Authorisation in the European Union (EU) for the treatment of schizophrenia in adults in March 2014.

Findings from the Citrome et al. analysis, a pooled post-hoc analysis of five short term studies, showed that lurasidone was significantly superior to placebo in reducing the Positive and Negative Syndrome Scale [PANSS] hostility item score from Week 1 (p=0.002) through Week 6 (p<0.001).1 Furthermore, patients receiving lurasidone experienced this reduction in hostility independently of change in other positive symptoms; after adjusting for change in positive symptoms, lurasidone significantly decreased hostility compared with placebo from Week 2 (p=0.014) through Week 6 (p<0.05).1

“Schizophrenia is a chronic mental illness characterized by episodes of behaviour disturbance that may be associated with psychotic features including hostility,” said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer of Sunovion Pharmaceuticals Inc. “The analyses presented at EPA contribute to the growing body of evidence supporting the efficacy of lurasidone in treating the symptoms associated with schizophrenia.”

Findings from the Inamdar et al. post-hoc analysis of pooled data from two long term studies, suggest that after 52 weeks, patients receiving lurasidone did not experience a clinically significant increase in prolactin levels.2 Prolactin data of patients receiving either quetiapine XR or risperidone were also reported.2 In the lurasidone group, median prolactin levels decreased by -8.00 pmol/L, compared to a decrease of -17.39 pmol/L and an increase of +385.00 pmol/L in the quetiapine XR and risperidone groups, respectively.2 A low rate of potential prolactin associated treatment-emergent adverse events (TEAEs), such as galactorrhea, amenorrhea and erectile dysfunction, was noted in the lurasidone treatment group.2

The results from the Palma dos Reis et al. post-hoc analysis of pooled data further support the clinical safety profile of lurasidone.3 The analysis showed that the incidence of TEAEs related to sexual dysfunction was low in lurasidone-treated patients in both the short- and long-term studies, respectively (0.5% and 2.2%).3 Hyperprolactinaemia is associated with the emergence of sexual dysfunction; this additional post-hoc analysis provides further information on the clinical relevance of lurasidone’s impact on prolactin levels.3
“Hyperprolactinaemia is a known adverse event of antipsychotics and longstanding elevation of prolactin levels can be clinically problematic,” said Rodrigo Palma dos Reis, M.D., Medical Director, Takeda. “Takeda and Sunovion are committed to improving treatment outcomes for patients with schizophrenia.”

Please see local SmPC for further information about Latuda.

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About Latuda® (lurasidone)

Latuda is an atypical antipsychotic, developed originally by Sumitomo Dainippon Pharma Co., Ltd. It has high affinity for dopamine D2, serotonin 5-HT2A and serotonin 5-HT7 receptors where it has antagonistic effects. In addition, Latuda is a partial agonist at the serotonin 5-HT1A receptor, and has no appreciable affinity for histamine (H1) or muscarinic (M1) receptors.

The recommended starting dose of Latuda is 37 mg once-daily with a meal. No initial dose titration is required. It is effective in a dose range of 37-148 mg once-daily. Maximum dosage is 148 mg per day.

Latuda was approved for the treatment of schizophrenia in adults in the US in October 2010, in Canada in June 2012, in Switzerland in August 2013, in Australia in March 2014 and in the EU in March 2014. Latuda is available in Switzerland, Norway, Finland, the Netherlands and the UK. Outside of Europe, Latuda is available in the US and Canada.

In March 2011, Sumitomo Dainippon Pharma Co., Ltd. and Takeda Pharmaceutical Company Limited in Japan 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. Sunovion Pharmaceuticals Europe Ltd., a wholly-owned direct subsidiary of Sunovion Pharmaceuticals Inc., is commercializing Latuda in the United Kingdom.

About the Abstracts

Citrome L et al. (0249) The post-hoc analysis included data that were pooled from five double-blind, placebo-controlled, 6-week studies of lurasidone 40-160 mg/d (37-148 mg/d) in patients with evidence of hostility at study baseline (PANSS hostility item score ≥2). Lurasidone was compared with placebo using mixed-model repeated-measure analysis, with and without adjustment for positive symptoms of schizophrenia and somnolence as covariates.
Inamdar I et al. (1723) The analysis included pooled data from two 52-week studies that evaluated the long-term safety and efficacy of lurasidone compared with quetiapine XR or risperidone in patients with schizophrenia. The data was reviewed post-hoc for prolactin levels and TEAEs considered to be related to hyperprolactinaemia.

Palma dos Reis et al. (1721) The post-hoc analysis included pooled data from 22 clinical studies. The studies were stratified into short term, long term and all Phase 2/3 lurasidone study pools. TEAEs relating to sexual dysfunction were defined as any adverse events related to sexual dysfunction starting on/after the first dose data and within seven days of treatment discontinuation.

About Schizophrenia

Schizophrenia is a severe, chronic mental illness which can affect both men and women. Patients with schizophrenia have a life span that is decreased by approximately 10–22.5 years compared with the general population, which can in part be due to the undesirable effects of antipsychotics such as weight gain and increased blood sugar.

Antipsychotic pharmacotherapy is the cornerstone of treatment for patients with schizophrenia, with agents generally classed as typical or atypical. Atypical agents are broadly considered to have tolerability benefits over typical agents. Switching antipsychotic medication is common in the treatment of patients with schizophrenia either due to residual or emergent symptoms, adverse events or tolerability issues.

Direct and indirect costs associated with caring for patients with schizophrenia are considerable and can include utilisation 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.

About Takeda Pharmaceuticals International GmbH

Headquartered in Zurich as a subsidiary of Takeda Pharmaceutical Company Limited, Osaka, Japan, the company 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. Areas of focus include cardiovascular and metabolic, oncology, respiratory and immunology, central nervous system, general medicine, and vaccines.

Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine. Through strategic acquisitions, Takeda has been transforming itself, broadening its therapeutic expertise and geographic outreach.

Additional information about Takeda is available through its corporate website, www.takeda.com.

About Sunovion Pharmaceuticals Inc.

Sunovion Pharmaceuticals Inc., an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma, and is headquartered in Marlborough, Mass. Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercialising therapeutic products that advance the science of medicine and improve the lives of patients and their families. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

References
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5. Ishibashi T et al. Pharmacological Profile of Lurasidone, a Novel Antipsychotic Agent with Potent 5-Hydroxytryptamine 7 (5-HT7) and 5-HT1A Receptor Activity. J Pharmacol Exp Ther 2010;334:171–81

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