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Multiple Scientific Posters Supporting the Efficacy, Safety and Tolerability of Once-daily Latuda® (lurasidone) are Presented at the 27th ECNP Congress

Berlin (ots/PRNewswire) - Takeda Pharmaceuticals International GmbH ("Takeda") and Sunovion
Pharmaceuticals Inc. ("Sunovion") presented new evidence supporting the use of Latuda(R) (lurasidone), an atypical antipsychotic treatment for adults with schizophrenia, during multiple poster sessions at the 27th European College of Neuropsychopharmacology (ECNP).

New data presented support Latuda's short and long-term efficacy, as well as preventing relapse.[1],[2],[3],[4],[5] These new data also support Latuda as a tolerable option for patients switching medication from risperidone, having a low propensity for weight gain with minimal effects on cardiovascular and metabolic parameters.[2]

Abstract [P.3.d.061]: 'Effect of lurasidone or risperidone on metabolic syndrome status in patients with schizophrenia: a post hoc analysis of a long-term study'

In one multi-regional, double blind study, Latuda was shown to reduce the risk of adult patients with schizophrenia developing metabolic syndrome,[1] which is associated with cardiovascular morbidity and mortality.[1] Results showed that among patients without metabolic syndrome at baseline, after 12 months of treatment the risk of developing metabolic syndrome was reduced by 48% in patients treated with flexibly dosed once-daily Latuda (37-111 mg/d) relative to patients treated with flexibly dosed risperidone (2-6 mg/d) (HR 0.52; 95% CI, 0.24-1.15).[1] In addition, in patients who completed 12 months of risperidone treatment, metabolic syndrome prevalence decreased after a switch to Latuda in a six-month open label extension study.[1] Furthermore, after 12 months of double-blind risperidone treatment, the prevalence of metabolic syndrome was 48.4%, which subsequently decreased to 38.5% after six months of open-label Latuda treatment.[1]

Abstract [P.3.d.062]: 'An open-label extension study of lurasidone in patients with schizophrenia previously randomized to lurasidone or risperidone'

For adult patients switching medication, Latuda was found to be a well-tolerated and efficacious option in a six-month open-label extension (OLE) study.[2] Results from this study showed that switching to Latuda after 12 months of double-blind treatment with risperidone was associated with a mean change in weight of -2.9 kg, whereas patients who continued on Latuda experienced a -0.6 kg mean weight loss after an additional six months of treatment at the study endpoint.[2] In addition, patients who switched from risperidone demonstrated a decrease in prolactin levels (median change from open-label extension study baseline to endpoint: men, -11.2 ng/mL; women, -30.8 ng/mL).[2]

"Due to the chronic nature of schizophrenia, clinicians need to consider not only the efficacy of an antipsychotic medication in managing patients' symptoms, but also the potential impact on metabolic syndrome," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion Pharmaceuticals Inc. "We are encouraged to see these long-term data, which show Latuda was both effective, well-tolerated and associated with a low propensity for metabolic syndrome."

Abstract [P.3.d.065]: 'Evaluation of daytime sleepiness in patients with schizophrenia treated with atypical antipsychotics'

Daytime sleepiness associated with antipsychotic treatment may adversely impact functional performance and quality of life.[3] A post-hoc analysis of a six-week, double-blind study in adult patients with schizophrenia compared the effects of Latuda and quetiapine XR on prospectively measured daytime sleepiness (also known as daytime somnolence or sedation).[3] Results demonstrated that daytime sleepiness improved in the Latuda and placebo-treated groups.[3] Daytime sleepiness worsened in the quetiapine XR treatment group when compared to placebo ($p=0.001$) and to either dose of Latuda ($p<0.01$).[3]

Abstract [P.3.d.060]: 'Efficacy of lurasidone in the treatment of schizophrenia with prominent negative symptoms: a post hoc analysis of five short-term trials'

Efficacy of Latuda in treating both positive and negative symptoms in acutely psychotic adult patients with schizophrenia was demonstrated in a post-hoc analysis of patients with prominent negative symptoms.[4] Patients with prominent negative symptoms at baseline

were identified as having a Positive and Negative Syndrome Scale (PANSS) negative subscale score greater than or equal to25 (median score) and a PANSS positive score <25 (median score).[4] The analysis showed that Latuda treatment in the prominent negative symptom group was associated with significantly greater week six improvement compared to placebo on the PANSS-negative subscale score (-6.3 vs -4.5; p<0.01).[4] Treatment with Latuda was well-tolerated in the prominent negative symptom group with relatively low discontinuation rates due to adverse events.[4]

Abstract [P.3.d.058]: 'Maintenance efficacy of lurasidone compared to higher doses of quetiapine XR in schizophrenia: results from a post hoc analysis'

A 12-month blinded, controlled study of Latuda vs quetiapine XR in adult patients with schizophrenia demonstrated Latuda was non-inferior to quetiapine XR in prevention of relapse.[5] In this post-hoc analysis, the maintenance efficacy of Latuda (37-148 mg/day) was compared to higher doses of quetiapine XR (600-800 mg/day).[5] The results of a Kaplan-Meier analysis showed that when compared to quetiapine XR, the probability of relapse was 23.7% for subjects receiving Latuda and 33.6% for quetiapine XR.[5] In this analysis, the remission rates, based on full Remission in Schizophrenia Working Group (RSWG) criteria requiring improvement for at least 6 months, were 61.9% for Latuda and 46.8% for quetiapine XR (p=0.056).[5]

"Schizophrenia is a condition that can have a devastating impact on people's lives. Both patients and their healthcare providers need a broader range of effective treatment choices to help better manage schizophrenia; these latest data further support the proven efficacy of Latuda in both the short and long-term treatment of adult patients with schizophrenia. Treatment with Latuda is also generally well-tolerated and is not likely to increase the risk for cardiometabolic disorders, which is additionally important for patients with related co-morbidities," said Rodrigo Palma dos Reis, M.D., Medical Director, Takeda.

In addition, new analyses of lurasidone data in adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression) were presented.[6],[7] Lurasidone is approved for the treatment of bipolar depression in the United States and in Canada under the trade name Latuda. Lurasidone is not currently approved for bipolar depression in Europe.

About Latuda(R) (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.[8] In addition, Latuda is a partial agonist at the serotonin 5-HT1A receptor,[8] and has no appreciable affinity for histamine (H1) or muscarinic (M1) receptors.[9]

The recommended starting dose of Latuda is 37 mg once daily.[10] No initial dose titration is required.[10] It is effective in a dose range of 37 to 148 mg once daily.[10] The Latuda Summary of Product Characteristics includes additional dosing information for special patient populations.

Lurasidone was launched as Latuda for the treatment of schizophrenia in adults in the United States in February 2011 and in Canada in September 2012 through Sunovion Pharmaceuticals Inc.'s subsidiary Sunovion Pharmaceuticals Canada Inc., in Switzerland in September 2013 through Takeda and in the UK in August 2014 through Sunovion Pharmaceuticals Europe Ltd. In Japan a Phase III clinical study is underway for the treatment of schizophrenia by Sumitomo Dainippon Pharma Co., Ltd.

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 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,[11],[12] which can in part be due to the undesirable effects of antipsychotics such as weight gain and increased blood sugar.[13]

Antipsychotic pharmacotherapy is the cornerstone of treatment for patients with schizophrenia, with agents generally classed as typical or atypical.[14] Atypical agents are broadly considered to have tolerability benefits over typical agents.[14] Switching antipsychotic medication is common in the treatment of patients with schizophrenia either due to residual or emergent symptoms, adverse events or tolerability issues.[15],[16]

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.[17],[18]Hospitalization associated with patient relapse can significantly increase costs associated with disease management in schizophrenia.[19]

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, http://www.takeda.com.

About Sunovion Pharmaceuticals Inc. Sunovion Pharmaceuticals Inc., an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma, 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 http://www.sunovion.com [http://c/Users/apikalov/AppData/Local/Microsoft/Windows/Temporary InternetFiles/koneill/Downloads/www.sunovion.com] .

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