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News Release

All Wales Medicines Strategy Group Recommends Atypical Antipsychotic LATUDA® ▼ (lurasidone) as a Treatment Option for Schizophrenia in Adults

London 16 March 2015 – Sunovion Pharmaceuticals Europe Ltd. is pleased to announce that the All Wales Medicines Strategy Group (AWMSG) has recommended LATUDA® (lurasidone) as an option for use within National Health Service (NHS) Wales for the treatment of schizophrenia in adults aged 18 years and over.[1] Both in short- and longer-term clinical studies, LATUDA was found to be effective in adult patients with schizophrenia and was generally well-tolerated with negligible effects on metabolic parameters, such as glucose and cholesterol.[3,4,5] The most common side effects (≥10%) of LATUDA seen in short- and longer-term studies include akathisia and somnolence.[2,5]

"The AWMSG decision is welcome news, as there is a need for effective treatments with low metabolic burden to manage the acute symptoms of schizophrenia across the whole country," said Professor David Taylor, Professor of Psychopharmacology at King's College, London. "Metabolic-related side effects can affect adherence to therapy, which is a significant problem in schizophrenia as lack of adherence can ultimately lead to relapse and subsequent hospitalisations."

The AWMSG recommendation was supported in part by the economic case submitted by Sunovion, showing that LATUDA is estimated to be more cost-effective compared with aripiprazole. The differences in total costs were primarily driven by relative rates of relapse and hospitalisations.

Schizophrenia is a devastating mental illness, affecting an estimated 30,000 people in Wales who will develop the illness during their lifetime, and can have a significant impact on the lives and families of those affected.[6] Symptoms are diverse and can include hallucinations, distorted perception of reality, cognitive difficulties and social withdrawal. Compared to the general population, people with schizophrenia have almost double the risk of metabolic syndrome and diabetes, as well as a higher risk of mortality due to cardiovascular disease.[7] People with schizophrenia have a reduced life span of approximately 10-22.5 years.[8,9]

Atypical antipsychotics may be associated with undesirable side effects, including weight gain, hyperglycaemia and lipid abnormalities. Such adverse effects are related to an increased risk of cardiovascular disease and diabetes.

“Prudent healthcare means doing what you can to provide the most appropriate treatment and support needed by the patient at the least burden to the health service. If there is a medication that reduces the need for patients to go into hospital, then the benefits to the health service are tangible and I’m glad to see that AWMSG has endorsed the use of LATUDA as a new treatment option for adults with

schizophrenia, which will provide additional choice for patients and their doctors," said Alun Thomas, Chief Executive of Hafal, Wales' leading charity for people with serious mental illness and their carers.

"We are pleased with the AWMSG recommendation for LATUDA as a treatment for use within NHS Wales for adult patients with schizophrenia," said Krithika Rajagopalan, Vice President Global Health Economics and Outcomes Research, Sunovion Pharmaceuticals Inc. "At Sunovion, we are committed to improving the lives of people suffering from severe mental illness such as schizophrenia and look forward to bringing this treatment to patients in Wales and to the healthcare professionals who treat them."

National Institute for Health and Clinical Excellence (NICE) has accredited the process used by the AWMSG to produce its final appraisal recommendation. In October 2014, the Scottish Medicines Consortium (SMC) also accepted LATUDA for use within NHS Scotland as an alternative treatment option in patients in whom it is important to avoid weight gain and metabolic adverse effects.

The marketing authorization for LATUDA in the EU was based on short- and long-term data, which found LATUDA to be effective in treating both the positive and negative symptoms in psychotic adult patients with schizophrenia.[3,4,10,11,12,13,14]

Please find links to the LATUDA Summary of Product Characteristics (SmPC) and the Prescribing Information at http://www.medicines.org.uk/emc/medicine/29125 and http://latuda.co.uk/prescribing-information/.

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NOTES TO EDITORS:

In the UK, the Committee for Medicinal Products for Human Use (CMHP) and the Medicines and Healthcare Products Regulatory Agency (MHRA) encourage the reporting of all suspected adverse reactions (side effects) to newer drugs and vaccines, which are denoted by an inverted, equilateral black triangle (▼). LATUDA carries a black triangle to denote additional monitoring is required in relation to adverse reactions.

About LATUDA® (lurasidone)

LATUDA is an atypical antipsychotic, developed originally by Sumitomo Dainippon Pharma Co., Ltd. with a high affinity for dopamine D_2, serotonin 5-HT_{2A} and serotonin 5-HT_7 receptors where it has antagonistic effects.[10] In addition, LATUDA is a partial agonist at the serotonin 5-HT_{1A} receptor and has no appreciable affinity for histamine (H_1) or muscarinic (M_1) receptors.[10]

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.[2]

LATUDA was approved for the treatment of schizophrenia in adults by the US Food and Drug Administration in October 2010, by Health Canada in June 2012, by the Swiss Agency for Therapeutic Products in August 2013, by the Australian Therapeutic Goods Administration in March 2014 and by the European Commission (EC) 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.

For more information about LATUDA, please visit www.latuda.co.uk.

About Schizophrenia

Schizophrenia is a severe, chronic mental condition that can affect both men and women.[7] Patients with schizophrenia have a life span that is decreased by approximately 10-22.5 years compared with the general population.[8,9]

Antipsychotic pharmacotherapy is the cornerstone of treatment for patients with schizophrenia, with agents generally classified as typical or atypical. Atypical agents are broadly considered to have tolerability benefits over typical agents.[15] Switching antipsychotic medication is common in the treatment of patients with schizophrenia either due to residual or emergent symptoms, adverse events or tolerability issues.[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] Hospitalisation associated with patient relapse can significantly increase costs associated with disease management in schizophrenia.[19]

About Sunovion Pharmaceuticals Europe Ltd.

Sunovion Pharmaceuticals Europe, headquartered in London, UK, is a wholly-owned direct subsidiary of Sunovion Pharmaceuticals Inc. Additional information about Sunovion Europe is available at www.sunovion.eu.

Sunovion Pharmaceuticals Inc., an indirect, wholly-owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is headquartered in Marlborough, Massachusetts, US. 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.

About Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan. Sumitomo Dainippon Pharma aims to produce innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma is based on the merger in 2005 between Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

Sunovion Pharmaceuticals Inc. is a US subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

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

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