UCB and Daiichi Sankyo announce Japanese approval of lacosamide (brand name VIMPAT®) as adjunctive therapy in the treatment of partial-onset seizures in adult patients with epilepsy

- **UCB and Daiichi Sankyo will jointly commercialize lacosamide in Japan**
- **Approval reinforces commitment of both companies to improve the lives of people in Japan living with epilepsy**

Tokyo (Japan), Brussels (Belgium), 4TH JULY 2016 – 08:30AM (CET) - Daiichi Sankyo Company, Limited ("Daiichi Sankyo"; TSE: 4568) and UCB Biopharma SPRL ("UCB") today announced the Japanese Ministry of Health, Labor and Welfare (MHLW) has granted approval for lacosamide (brand name VIMPAT®) as an adjunctive therapy in the treatment of partial onset seizures with or without secondary generalization in adult patients with epilepsy who have not obtained sufficient response to other antiepileptic drugs.

"Today's announcement reinforces our commitment to improving the lives of people living with epilepsy around the world and to increasing patient access to our core medicines", explained Jean-Christophe Tellier, CEO, UCB. "This is an example of our collaborative, patient-led and science-driven approach delivering benefits by providing additional treatment options for people living with epilepsy. We look forward to successfully launching lacosamide in Japan and continuing our partnership with Daiichi Sankyo."

"Daiichi Sankyo is very excited to work with long-time valued partner, UCB, to further contribute to the management of epilepsy in Japan by adding lacosamide as a new therapeutic option to our existing Central Nervous System (CNS) portfolio", explained Joji Nakayama, Representative Director, President and CEO, Daiichi Sankyo. "Lacosamide's well-established efficacy and tolerability profile will provide doctors in Japan and their patients with an additional treatment option to help manage their condition. We very much look forward to realizing this opportunity."

DaiichiSankyo and UCB will partner to commercialize lacosamide in Japan, as agreed previously by both companies in 2014. UCB will manufacture and supply the product; Daiichi Sankyo will manage distribution and book sales in Japan, with both companies promoting lacosamide in Japan.

About Epilepsy[1,2]

Epilepsy is a disease of the brain affecting approximately 65 million people worldwide. It is thought to affect approximately 1 million people in Japan. It is defined as either the occurrence of two or more unprovoked seizures >24 hours apart or one unprovoked (or reflex) seizure and a probability of further seizures occurring over the next 10 years that is similar to the general recurrence risk (at least 60%) after two unprovoked seizures or diagnosis of an epilepsy syndrome. Although epilepsy may be linked to factors such as health conditions, race and age, it can develop in anyone at any age, and approximately 1 in 26 people will develop epilepsy in their lifetime.

About UCB in Epilepsy

UCB has a rich heritage in epilepsy with more than 20 years of experience in the research and development of anti-epileptic drugs. As a company with a long-term commitment to epilepsy research, our goal is to address unmet medical needs. Our scientists are proud to contribute to advances in the understanding of epilepsy and its treatment. We partner and create super-networks with world-leading scientists and clinicians in academic institutions, pharmaceutical companies and other organizations who share our goals. At UCB, we are inspired by patients and driven by science in our commitment to support patients with epilepsy.

About VIMPAT® (lacosamide)

VIMPAT® (film-coated tablets) is approved in Japan as follows:

- Indications: Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalization in patients with epilepsy who have not obtained sufficient response to other antiepileptic drugs.
- Dosage and administration: For adults, the recommended starting dose of lacosamide is 100mg/day, which should be increased to an initial therapeutic dose of 200mg/day at intervals of at least 1 week, each given orally in 2 divided doses. However, depending on response and tolerability, the maintenance dose can be further increased to a maximum recommended daily dose of 400mg, and dose increments should be made within doses of 100 mg/day at intervals of at least 1 week.

Important Safety Information about VIMPAT® (lacosamide) in Japan

Vimpat is contraindicated in Japan in :

- patients with a history of hypersensitivity to lacosamide or any of the excipients.

- Patients with severe hepatic impairment (In the absence of clinical experience, the risk of elevated blood lacosamide concentration cannot be denied in these patients).

Precautions related to Dosage and Administration

For patients with the creatinine clearance less than 30 ml/min and in patients with endstage renal disease, lacosamide treatment should be made with caution by, for example, limiting the maximum daily dose of 300 mg. For patients requiring haemodialysis, in addition to a daily dose, a supplement of up to 50% of the divided daily dose directly after the end of haemodialysis should be considered.

For patients with mild or moderate hepatic impairment (Child-Pugh A and B), lacosamide treatment should be made with caution by, for example, limiting the maximum dose of 300 mg.

Careful Administration (lacosamide should be administered with care in the following patients.)

(1) Patients with severe renal impairment or patients with endstage renal disease.

(2) Patients with hepatic impairment.

(3) Patients with a history of cardiac conduction disorders or severe cardiac diseases (e.g., myocardial infarction and heart failure), sodium channelopathies (e.g., Brugada syndrome), on concomitant medications that may prolong PR interval (atrioventricular block or similar conditions may develop due to the PR interval prolongation potential of lacosamide, see the Important Precautions section).

(4) Elderly patients

Important Precautions

(1) Worsening of epileptic seizures or status epilepticus may be seen when lacosamide is abruptly reduced or discontinued after continuous use. If lacosamide has to be discontinued, take extra caution such as gradual dose reduction over at least one week.

(2) Some patients might experience dizziness, blurred vision, drowsiness and decreased attention, concentration, reflex movement, etc. Therefore, these patients taking lacosamide should be instructed not to operate machinery, such as vehicle, that involves risk.

(3) Because PR interval prolongation may occur during treatment with lacosamide, pay attention to the development of conditions related to second-degree or higher atrioventricular block etc. (e.g., rapid, slow or irregular pulse, feeling of lightheaded, fainting, palpitations, shortness of breath). Patients should be counseled to seek medical advice should any of these symptoms occur. Carefully monitor the condition and changes in signs and symptoms, particularly in patients with a history of cardiac conduction disorders or severe cardiac diseases (e.g., myocardial infarction and heart failure), sodium channelopathies (e.g., Brugada syndrome), and on concomitant medications that may prolong PR interval by, for example, obtaining an ECG before the start of treatment with lacosamide, and after lacosamide is titrated to steady state maintenance dose.

(4) Psychiatric symptom, such as irritability, excitement and aggression may occur and may lead to suicide attempt. Carefully monitor the condition and changes in signs and symptoms.

(5) Inform the patients and their relatives deeply of the possibility of development of psychiatric symptoms, such as aggression and suicide attempt. Direct them to keep contact closely with their physician.

(6) Lacosamide can cause eye disorders such as diplopia and blurred vision. The physician should check for eye disorders by, for example, inquiring patients about them during interview. The physician should take appropriate actions if abnormalities are found.

Clinically significant adverse reactions

1) Atrioventricular block, bradycardia, syncope (less than 1%)

Lacosamide can prolong PR interval, which may lead to atrioventricular block, bradycardia or syncope, may occur. Close observation should be made. In the event of abnormalities, the drug should be discontinued and appropriate evaluation and treatment should be undertaken.

2) Toxic epidermal necrosis (TEN), Muco-cutaneous-ocular syndrome (Stevens-Johnson syndrome) (Incidence unknown*)

Patients should be observed carefully. If abnormality such as Fever, Erythema, Bulla/Erosion, Pruritis, Pain pharynx, Ocular hyperaemia, Stomatitis, etc. is noted, treatment should be discontinued and appropriate measures taken

3) Drug-induced hypersensitivity syndrome (Incidence unknown*)

Rash and pyrexia may be observed as initial symptoms, followed by delayed serious hypersensitivity symptoms associated with hepatic function disorder, swollen lymph nodes, white blood cell increased, eosinophils increased and atypical lymphocytes etc.; therefore, careful observation should be made. In case such symptoms appear, treatment should be discontinued and adequate measures and treatment should be undertaken. Relevant syndrome is frequently accompanied by virus re-activation, including human herpes virus-6 (HHV-6). The patient's condition should be carefully observed for the reason that such symptoms of rash, pyrexia and hepatic function disorder may become recurrent or prolong even after treatment withdrawal.

4) Agranulocytosis (Incidence unknown*)

Agranulocytosis has been reported. Close observation should be made. In the event of abnormalities, the drug should be discontinued and appropriate evaluation

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases in immunology and neurology. With more than 7500 people in approximately 40 countries, the company generated revenue of €3.9 billion in 2015. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage

in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com.

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