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Press Release

Daiichi Sankyo Company, Limited

UCB Japan Co., Ltd.

Antiepileptic lacosamide filed for partial amendment of approval to add a new indication in Japan

Daiichi Sankyo Company, Limited (headquarters: Chuo-ku, Tokyo; hereafter referred to as “Daiichi Sankyo”) and UCB Japan Co., Ltd. (headquarters: Shinjuku-ku, Tokyo; hereafter referred to as “UCB Japan”; when referring to the global UCB group, “UCB”) are pleased to announce today that they filed an application for partial amendment of approval to use lacosamide (brand name: VIMPAT® Tablets 50 mg and 100 mg) in monotherapy for partial-onset seizure (including secondary generalized seizures) in patients with epilepsy.

This application is based on the results of Phase 3 international clinical trial[*1] in 888 adult patients (aged 16 and over), including Japanese patients with newly or recently diagnosed epilepsy. Monotherapy with lacosamide showed non-inferiority to monotherapy using controlled-release carbamazepine formulation in terms of the primary efficacy endpoint. The adverse event (AE) profile was comparable to that observed in previous lacosamide trials, including dizziness, headache, fatigue, somnolence and nausea[*1,2].

Daiichi Sankyo and UCB expect lacosamide to be able to contribute to patients and healthcare providers by offering a new treatment option.

About lacosamide

Lacosamide is a novel antiepileptic drug with a new mechanism of action which differs from that of existing antiepileptic drugs[*3,4,5]. Specifically, it suppresses excessive excitation of neurons by selectively promoting gradual inactivation of potential-dependent Na channels[*6]. Its usefulness was demonstrated in a Japan-China collaborative Phase 3 clinical trial in adult patients (aged 16 and over) with partial-onset seizures including Japanese patients[*7] and a long-term extended trial[*8]. Based on results of these clinical trials, lacosamide was approved in Japan for “adjuvant therapy for partial-onset seizures in patients with epilepsy” in July 2016. In Japan, Daiichi Sankyo and UCB will partner to commercialize lacosamide in Japan, as agreed previously by both companies in November 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. Lacosamide was approved for “monotherapy for partial-onset seizures in patients with epilepsy” in the USA in August 2014.

About epilepsy

Epilepsy affects approximately 65 million people around the world with a prevalence of about 1%. It may occur over a wide age range from infants to senior citizens and its incidence does not vary much across countries, geographies, genders or races. The number of patients with epilepsy is estimated to total about one million in Japan with approximately 57.000 patients every year[*9]. Epilepsy is a disease with unmet medical needs even today with a great majority of patients needing long-term pharmacotherapy[*10] and over 30% of patients being reportedly unable to adequately control seizures despite treatment with existing antiepileptic drugs[*11]. Seizures associated with epilepsy are classified into three major groups based on their clinical symptoms: partial-onset seizures (which may sometimes progress to secondary generalized seizures), generalized seizures, and unclassified seizures. Partial-onset seizures show the highest incidence among these three types accounting for approximately 60% of the total.

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.

Reference

*1: Baulac, M. et al., Efficacy and tolerability of lacosamide monotherapy in patients with newly diagnosed epilepsy: A randomized double-blind trial versus controlled-release carbamazepine. Abstract presented at EAN 2016.

*2: VIMPAT Summary of Product Characteristics (SmPC) for European Union. Accessed 18 May 2016 from http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000863/WC500050338.pdf.

*3: Vilin YY. et al : Cell Biochem Biophys. 35(2), 171-190, 2001

*4: Beyreuther BK. et al : CNS Drug Rev. 13(1), 21-42, 2007

*5: Rogawski MA. et al : Epilepsy Res. 110, 189-205, 2015

*6: Errington AC. et al : Mol Pharmacol. 73(1), 157-169, 2008

*7: Application dossier (placebo-controlled comparative study on adjunctive therapy for partial-onset seizures in Japan and China) (in Japanese)

*8: Application dossier (long-term extended study on adjunctive therapy for partial-onset seizures in Japan and China) (in Japanese)

*9: The Japan Epilepsy Society: Guidebook for Epileptologists (in Japanese), Shindan to Chiryo Sha Inc., 2014

*10: Perucca E. : Baillière's Clin Neurol. 5(4), 693-722, 1996

*11: Kwan P. et al : N Engl J Med. 342(5), 314-319, 2000

About Daiichi Sankyo Group

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.

About UCB

UCB, based in 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 including those of the central nervous system or the immune system. 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).

Established in 1988, UCB Japan markets a number of products. The anti-epileptic drug E Keppra® and the TNF-α inhibitor Cimzia®, will be a platform for further growth. As a biopharma leader, UCB Japan is dedicated to making a continuing contribution to the treatment and health of patients with severe diseases such as neurology and immunology/inflammatory diseases.

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