August 31, 2016

Press Release

Daiichi Sankyo Company, Limited

UCB Japan Co., Ltd.

Antiepileptic Drug Vimpat® Tablets 50 mg and 100 mg have been launched.

Daiichi Sankyo Company, Limited (headquarters: Chuo-ku, Tokyo; hereinafter referred to as “Daiichi Sankyo”) and UCB Japan Co., Ltd. (headquarters: Shinjuku-ku, Tokyo; hereinafter referred to as “UCB Japan”; when referring to the global UCB group, “UCB”) are pleased to announce today that they have launched Vimpat® Tablets 50 mg and 100 mg (generic name: lacosamide; date of approval: July 4, 2016; date of listing in the NHI reimbursement price list in Japan: Aug 31, 2016)

Vimpat® is a novel antiepileptic drug with a new mechanism of action which differs from that of existing antiepileptic drugs[*1,2,3]. Specifically, it suppresses excessive excitation of neurons by selectively promoting gradual inactivation of potential-dependent Na channels[*4]. 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[*5] and a long-term extended trial[*6]

Vimpat® has been approved over 70 countries since it was first approved in August 2008 in Europe, followed by the USA in October of the same year.

Daiichi Sankyo and UCB partner to commercialize Vimpat® in Japan, as agreed previously by both companies in November 2014. UCB manufactures and supplies the product; Daiichi Sankyo manages distribution and book sales in Japan, with both companies promoting Vimpat® in Japan.

Daiichi Sankyo and UCB are confident that Vimpat® will contribute to patients and healthcare providers in Japan by offering a new treatment option in adjuvant therapy for partial-onset seizures in epilepsy patients.

Product Profile

Brand name	Vimpat® Tablets 50mg・100mg
Generic name (JAN)	Lacosamide
NHI price	Vimpat® Tablets 50 mg： 215.60 yen per tablet Vimpat® Tablets 100 mg： 352.00 yen per tablet
Indication	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.
Date of approval	July 4, 2016
Date of listing in the NHI reimbursement price list in Japan	Aug 31, 2016
Date of launch	Aug 31, 2016
Manufactured by	UCB Japan Co., Ltd.
Marketed by	Daiichi Sankyo

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[*7]. Epilepsy is a disease with unmet medical needs even today with a great majority of patients needing long-term pharmacotherapy[*8] and over 30% of patients being reportedly unable to adequately control seizures despite treatment with existing antiepileptic drugs[*9]. 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: Vilin YY. et al : Cell Biochem Biophys. 35(2), 171-190, 2001

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

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

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

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

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

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

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

*9: 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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