



February 27, 2020

Press Release

UCB Japan Co., Ltd.  
DAIICHI SANKYO Company, Limited

**Anti-epilepsy Drug VIMPAT<sup>®</sup>, Submission for  
Supplemental Application for Approval in Japan**

UCB Japan Co., Ltd, (headquarters: Shinjuku-ku, Tokyo; president: Kanako Kikuchi; hereafter referred to as "UCB Japan"; when referring to the global UCB group, "UCB") and Daiichi Sankyo Company, Limited (headquarters: Chuo-ku, Tokyo; president: Sunao Manabe; hereafter referred to as "Daiichi Sankyo") are pleased to announce today that a supplemental application for VIMPAT<sup>®</sup> (generic name: lacosamide) was filed in Japan to expand the indication for adjunctive therapy for tonic-clonic seizures in epilepsy patients as a partial change in approved items of the manufacturing and marketing approval.

This application is based on the results of a multinational PIII clinical trial in 242 adult and pediatric epilepsy patients aged 4 years and older (including Japanese patients) with tonic-clonic seizures showing inadequate control under treatment with existing anti-epileptic drugs. The study met its primary endpoint (the time to the second tonic-clonic seizure during the 24-week evaluation period, i.e., the risk of developing the second tonic-clonic seizure) showing statistically significant difference between patients groups administered with lacosamide vs placebo. No new concerns about safety were raised.

UCB and Daiichi Sankyo expect that they can contribute to patients by offering a new treatment option for epilepsy with this drug.

### **About VIMPAT® (generic name: lacosamide)**

VIMPAT® suppresses excessive excitation of neurons by selectively promoting gradual inactivation of potential-dependent Na channels <sup>1</sup>. In Japan, VIMPAT® is approved for 50mg and 100 mg tablets, dry syrup 10% and iv drip infusion 200 mg as well as iv drip infusion 100 mg (not yet listed in the NHI).

In Japan, UCB and Daiichi Sankyo concluded a licensing agreement in November 2014. Based on that agreement, UCB manufactures and supplies the product, while Daiichi Sankyo manages distribution and books sales. Promotion is carried out jointly by both companies.

### **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 infancy to old age 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 new patients every year <sup>2</sup>. Epilepsy is a disease with unmet medical needs even today, with a large majority of patients needing long-term pharmacotherapy <sup>3</sup> and over 30% of patients reportedly being unable to adequately control seizures despite treatment with existing antiepileptic drugs <sup>4</sup>.

Seizures associated with epilepsy are classified into three major groups based on their clinical symptoms: partial-onset seizures (which sometimes progress to secondary generalized seizures), generalized seizures, and unclassified seizures. Upon onset of tonic-clonic seizures, a type of generalized seizures, patients suddenly lose consciousness and show generalized rigidity and violent seizures. These seizures reportedly account for 60% of generalized seizures.

### **About UCB in Epilepsy**

UCB has a longstanding commitment to improving the lives of people with epilepsy around the world. With over 20 years of experience in the research and development of antiepileptic drugs, our goal is to become a preferred partner for the global epilepsy community, improving knowledge about and access to effective solutions to help patients better manage their individual epilepsy journeys. We strive to 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 people with epilepsy.

## Reference

1. Errington AC. et al. Mol Pharmacol. 2008;73(1):157-169.
2. The Japan Epilepsy Society: Guidebook for Epileptologists (in Japanese), Shindan to Chiryō Sha Inc., 2014
3. Perucca E. Baillière's Clin Neurol. 1996;5(4):693-722.
4. Kwan P. et al. N Engl J Med. 2000;342(5):314-319.

## About UCB

UCB, Brussels, Belgium ([www.ucb.com](http://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 of the immune system or of the central nervous system. With around 7 500 people in approximately 40 countries, the company generated revenue of € 4.6 billion (approximately 600 billion yen) in 2018. UCB is listed on Euronext Brussels (symbol: UCB).

Since 1988, UCB Japan is contributing to medicine and health in Japan through delivering medicines for treating epilepsy, rheumatoid arthritis and psoriasis. As a biopharma leader, UCB Japan is dedicated to making a continuing contribution to the treatment and health for patients in Japan by providing new options for patients who have not improved with existing treatment.

## About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 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 cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: [www.daiichisankyo.com](http://www.daiichisankyo.com).

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