



January 8, 2019

Press Release

UCB Japan Co., Ltd.
Daiichi Sankyo Company, Limited

**Pediatric Dosage and Administration Approved for
Anti-epileptic Drug VIMPAT® Tablets 50 mg and 100 mg**

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 VIMPAT® Tablets 50 mg and 100 mg (generic name: lacosamide) has been approved, adding a new dosage and administration regimen for pediatric patients (4 years and older) to the indication of the "partial onset seizures of epilepsy patients with or without secondary generalization".

Epilepsy is a common, chronic neurological disorder that affects approximately one million people in Japan¹ and 65 million people worldwide, with almost half of cases diagnosed during childhood.² Since epilepsy that occurs during childhood is quite variable and may be associated with a number of comorbidities, there is a need for new treatment options that may provide seizure control with a low side effect profile.

The new dosage and administration regimen approved for children is based on the results of a number of clinical studies including a Phase 2 multinational study conducted in Japanese and non-Japanese pediatric epilepsy patients³ and a Phase 3 overseas clinical trial⁴.

UCB and Daiichi Sankyo aim to make greater contributions to epilepsy patients and healthcare professionals by offering this new treatment option to children with epilepsy.

Product Outline

Product name	Vimpat® Tablets 50mg- 100mg
Generic name (JAN)	Lacosamide
Indications	Partial onset seizures of epilepsy patients with or without secondary generalization
Dosage and administration (additions underlined)	<p><u>Adults:</u> The recommended starting dose of lacosamide is 100 mg/day, which should be increased to an initial therapeutic dose of 200 mg/day at intervals of at least 1 week, each given orally in two divided doses. However, depending on response and tolerability, the maintenance dose can be further increased to a maximum recommended daily dose of 400 mg, and dose increments should be made within doses of 100 mg/day at an interval of at least 1 week.</p> <p><u>Children:</u> The recommended starting dose of lacosamide for children aged ≥ 4 years is 2 mg/kg/day, which should be increased to an initial therapeutic dose of 6 mg/kg/day for children weighing less than 30kg and 4 mg/kg/day for children weighing from 30kg to under 50kg by 2mg/kg/day at intervals of at least 1 week, each given orally in two divided doses. However, depending on response and tolerability, the maintenance dose can be further increased by 2 mg/kg/day every week. In children weighing less than 30 kg, due to an increased clearance compared to adults, a maximum dose of 12 mg/kg/day is recommended. In children weighing from 30 to under 50 kg, a maximum dose of 8mg/kg/day is recommended. The dose increments should be made within doses of 2 mg/kg/day at an interval of at least 1 week. Dosage in children weighing 50 kg or greater is the same as in adults.</p>
Date of approval	4 July, 2016
Date of listing in the NHI price	31 August, 2016
Date of initial marketing in Japan	31 August, 2016
Additional indication approved for manufacture and marketing	8 January, 2019
Manufacture and marketing:	UCB Japan Co., Ltd.
Marketing	Daiichi Sankyo Co., Ltd.

About VIMPAT® (generic name: lacosamide)

VIMPAT® suppresses excessive excitation of neurons by selectively promoting gradual inactivation of potential-dependent Na channels⁵. VIMPAT® was approved in Japan as an adjunctive therapy for partial-onset seizures in adult patients with epilepsy in July 2016. VIMPAT® was also approved for use as a “monotherapy for partial-onset seizures in adult patients with epilepsy” in August 2017 and a new dosage and administration regimen was added to the indication of the “partial onset seizures of epilepsy in pediatric epilepsy patients (4 years and older) in adjunct therapy or monotherapy” in January 2019.

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 ¹. Epilepsy is a disease with unmet medical needs even today, with a large majority of patients needing long-term pharmacotherapy ⁶ and over 30% of patients reportedly being unable to adequately control seizures despite treatment with existing antiepileptic drugs ⁷.

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. 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 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. Japan Epilepsy Society: Guide Book for Epileptologists. Shindan to Chiryō Sha, Inc. 2014
2. Shinnar, S., Pellock, J.M. Update on the epidemiology and prognosis of pediatric epilepsy. *J Child Neurol.* 2002;17(1):S4-17.
3. Application dossier (A long-term study for adjunctive therapy for partial-onset seizures in pediatric subjects)
4. Application dossier (A placebo-controlled study for adjunctive therapy for partial-onset seizures in pediatric subjects)
5. Hong et al. *Epilepsy Res.* 2016;127:267-275.
6. Perucca E. *Baillière's Clin Neurol.* 1996;5(4):693-722.
7. Kwan P. et al. *N Engl J Med.* 2000;342(5):314-319.

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 or neurology. With more than 7 500 people in approximately 40 countries, the company generated revenue of € 4.5 billion (approximately ¥570 billion) in 2017. 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 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 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.

UCB Japan Co., Ltd., Communications Dept.

Tel: 03-6864-7633

Daiichi Sankyo Co., Ltd., Corporate Communications Dept.

Tel: 03-6225-1126