March 25, 2019

Press Release

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

Anti-epilepsy Drug VIMPAT® for I.V. infusion 200mg Launched 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 the anti-epilepsy drug VIMPAT® for I.V. infusion 200mg (generic name: lacosamide) has been launched in Japan.

VIMPAT® for I.V. infusion 200mg is a new dosage form developed as an alternative to lacosamide oral formulations in patients when oral administration is temporarily not feasible for the partial onset seizures of epilepsy patients with or without secondary generalization. Consequently, this I.V. infusion dosage form can contribute to the continuous treatment of epilepsy patients.

UCB and Daiichi Sankyo aim to make greater contributions to epilepsy patients and healthcare professionals by offering this new VIMPAT® injectable treatment option in Japan in addition to VIMPAT® Tablets and VIMPAT® Dry syrup.

Product Outline

Product name	Vimpat® for I.V. infusion 200mg
Generic name (JAN)	Lacosamide
Indications	Alternative to lacosamide oral formulations in patients when oral administration is temporarily not feasible for the following indication: Partial onset seizures of epilepsy patients with or without secondary generalization
Dosage and administration	When switching from oral lacosamide, The usual intravenous administration should be equivalent to the total daily dosage and frequency of the oral administration, given over a period of 30 minutes to 60 minutes per dose. When lacosamide is intravenously administered before using oral lacosamide formulation, Adults: 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, in two divided doses administered intravenously over a period of 30 minutes to 60 minutes. Children: 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 30 kg and 4 mg/kg/day for children weighing from 30 kg to under 50 kg by 2mg/kg/day at intervals of at least 1 week, in two divided doses administered intravenously over a period of 30 minutes to 60 minutes. Dosage in children weighting 50 kg or greater is the same as in adults. In either case, dose of lacosamide may be modified depending on response and tolerability, however, maximum recommended daily doses, and methods of dose increments should be as follows.

	Adults: 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. Children: 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 8 mg/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. Maximum recommended daily dose and methods of dose increments in children weighting 50 kg or greater is the same as in adults.
Date of approval	January 8, 2019
Date of listing in the NHI price	February 26, 2019
NHI drug price	Vimpat® for I.V. infusion 200mg: 1 bottle 4,252yen
Date of initial marketing in Japan	March 25, 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 channels [1]. VIMPAT® was approved in Japan for use 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 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” in January 2019. In addition, dry syrup and iv drip infusion formulations were approved 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 [2]. Epilepsy is a disease with unmet medical needs even today, with a large majority of patients needing long-term pharmacotherapy [3] and over 30% of patients reportedly being unable to adequately control seizures despite treatment with existing antiepileptic drugs [4].

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. Errington AC. et al. Mol Pharmacol. 2008;73(1):157-169.
2. The Japan Epilepsy Society: Guidebook for Epileptologists (in Japanese), Shindan to Chiryo 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) 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). 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.

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