September 1, 2017

Press Release

Daiichi Sankyo Company, Limited

UCB Japan Co., Ltd.

Restriction on prescription period lifted for antiepileptic VIMPAT® Tablets 50 mg and 100 mg

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 the Ministry of Health, Labor and Welfare issued a notification announcing the lifting of “the 14-day restriction on the prescription period” for the antiepileptic VIMPAT® Tablets 50 mg and 100 mg (generic name: lacosamide).

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 which included Japanese patients[*5], and though a long-term extended trial[*6].

Daiichi Sankyo and UCB expect VIMPAT® to be able to further contribute to patients and healthcare providers in Japan as a result of the lifting of the restriction on its prescription period.

Product Profile

Brand name	VIMPAT® Tablets 50 mg and 100 mg
Generic name (JAN)	Lacosamide
Indication	Partial-onset seizures (including secondary generalized seizures) in patients with epilepsy
Dosage and administration	For 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, 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.
Date of approval	July 4, 2016
Date of listing in the NHI reimbursement price list	August 31, 2016
Date of launch	August 31, 2016
Date of partial amendment of approval	Monotherapy indication: August 25, 2017
Marketing authorization holder	UCB Japan Co., Ltd.
Marketed by	Daiichi Sankyo Company, Limited

About VIMPAT® (generic name: lacosamide)

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]. Based on results of these clinical trials, VIMPAT® was approved in Japan for "adjunctive therapy for partial-onset seizures in patients with epilepsy" in July 2016. VIMPAT® was approved for "monotherapy for partial-onset seizures in patients with epilepsy" in the USA in August 2014, in Europe in December 2016, and in Japan in August 2017.
In Japan, Daiichi Sankyo and UCB 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 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 new 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 reportedly being 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 the field of epilepsy with more than 20 years of experience in research and development of anti-epileptic drugs. As a company with a long-term commitment to epilepsy research, our goal is to provide solutions that help patients improve their ADL with a focus on unmet medical needs. Our scientists are proud to contribute to advances in the understanding of epilepsy and its treatment. We share goals, cooperate, and create advanced networks with world-leading scientists and clinicians in academic institutions, pharmaceutical companies and other organizations. At UCB, we are inspired by patients and driven by science in our commitment to support patients with epilepsy.

References

*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

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.

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 7,500 people in approximately 40 countries, the company generated revenue of € 4.2 billion (about ¥500 billion) in 2016. UCB is listed on Euronext Brussels (symbol: UCB).

Established in 1988, UCB Japan markets a number of products. The anti-epileptic drug E Keppra®, VIMPAT® 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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