

Application for Marketing Authorization for Lacosamide (Generic Name) in Japan for the Treatment of Epilepsy

Daiichi Sankyo Company, Limited ("Daiichi Sankyo"; headquarters: Chuo-ku, Tokyo) and UCB Japan Co., Ltd. ("UCB Japan", headquarters: Shinjuku-ku, Tokyo, and solely "UCB" refers to the whole UCB group) announced on 26 June, 2015 that UCB Japan has applied for marketing authorization for lacosamide in Japan as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalization in patients who have not obtained sufficient response to other antiepileptic drugs.

This application is based on the results of a PIII clinical trial in Japanese and Chinese adult patients with partial-onset seizures which UCB announced in October 2014¹. At 200 mg or 400 mg per day, lacosamide significantly reduced the incidence of partial-onset seizures compared to placebo. Adverse events observed in this study were similar to those reported to date in overseas clinical studies and post-marketing surveillance and raised no new concerns about safety².

When marketing authorization is obtained, UCB Japan Co., Ltd. ("UCB Japan") and Daiichi Sankyo will take care of manufacturing and sales/distribution, respectively, in Japan, while the two companies will jointly carry out promotion based on the joint commercialization agreement Daiichi Sankyo and UCB concluded in November 2014.

Daiichi Sankyo and UCB Japan shall contribute to epilepsy patients and healthcare providers in Japan by providing a new option for adjunctive therapy in the treatment of partial-onset seizures.

About Epilepsy³⁻⁵

Epilepsy is a disease of the brain that affects approximately 65 million people worldwide. It is defined as either the occurrence of two or more unprovoked seizures >24 hours apart or one unprovoked (or reflex) seizure and a probability of further seizures occurring over the next 10 years that is similar to the general recurrence risk (at least 60%) after the occurrence of two unprovoked seizures or diagnosis of epilepsy syndrome. Although epilepsy may be linked to factors such as health conditions, race and age, it can develop in anyone at any age, and approximately 1 in 26 people will develop epilepsy in their lifetime.

About UCB and Epilepsy

UCB has a rich heritage in the field of epilepsy with over 20 years of experience in the research and development of novel antiepileptic drugs. Every day, thousands of people use anti-epileptic drugs from our portfolio to help control their seizures. As a company with a long-term commitment to epilepsy research, our goal is to address unmet medical needs and deliver solutions that improve patients' lives. 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 continuous commitment to support patients with epilepsy.

About Lacosamide (generic name)

Lacosamide was first launched in the European Union in September 2008 under the brand name Vimpat® as adjunctive therapy for the treatment of partial-onset seizures with or without secondary generalization in adult and adolescent (16-18 years) patients with epilepsy. At present, lacosamide is available in 46 countries worldwide. In the US and Europe it is available as film-coated tablets, syrup and solution for i.v. infusion. Lacosamide solution for i.v. infusion is an alternative when oral administration becomes temporarily not feasible. UCB holds the world-wide rights for development, manufacturing and marketing of Lacosamide. It is currently not approved in Japan for the treatment of epilepsy.

References

1. ClinicalTrials.gov Identifier: NCT01710657: Accessed 23rd November 2014 from <http://www.clinicaltrials.gov/ct2/show/NCT01710657?term=NCT01710657&rank> = Accessed
2. VIMPAT® Summary of Product Characteristics. Accessed 23rd November 2014 from http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000863/WC500050338.pdf
3. Fisher, R.S., et al., ILAE Official Report: A practical clinical definition of epilepsy. *Epilepsia*, 2014. 55(4): 475-82.
4. Institute of Medicine. *Epilepsy Across the Spectrum. Promoting Health and Understanding*, Washington, DC: The National Academic Press, 2012 brief report. Accessed 17th November 2014 from http://www.iom.edu/~media/Files/Report%20Files/2012/Epilepsy/epilepsy_rb.pdf
5. The Epilepsy Foundation of America. Who gets epilepsy? Accessed 17th November 2014 from <http://www.epilepsy.com/learn/epilepsy-101/who-gets-epilepsy>

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 17,000 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 its strong portfolio of medicines for hypertension, dyslipidemia, bacterial infections, and thrombotic disorders, the Group's research and development is focused on bringing forth novel therapies in cardiovascular-metabolic diseases, pain management, and oncology, including biologics. 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 8500 people in approximately 40 countries, the company generated revenue of € 3.4 billion in 2013. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @ ucb_news
Established in 1988, UCB Japan markets a number of products including the allergic disease treatment Zyrtec[®] Tablets (cetirizine). The anti-epileptic drug E Keppra[®] (levetiracetam), which was launched in September 2010 and the TNF- α inhibitor Cimzia[®], will be a platform for further growth. As a specialty biopharma, UCB Japan is dedicated to making a continuing contribution to the treatment and health of patients with severe diseases such as central nervous system (CNS) disorders and immunology/inflammatory diseases.

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