



21 December, 2015 Daiichi Sankyo Company, Limited UCB Japan Co., Ltd.

# Results of Analysis of Data from Clinical Trial of Lacosamide (Generic Name) Announced at 2015 Annual Meeting of the American Epilepsy Society

Daiichi Sankyo Company, Limited ("Daiichi Sankyo"; headquarters: Chuo-ku, Tokyo) and UCB Japan Co., Ltd. ("UCB Japan", headquarters: Shinjuku-ku, Tokyo, and soley "UCB" refers to the whole UCB group) announced that the results of analysis of data from the clinical trial of lacosamide (Generic Name) were presented at 2015 Annual Meeting of the American Epilepsy Society held on December 4-8, 2015, in Philadelphia, USA.

This Phase III trial was a double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of adjunctive lacosamide treatment in Chinese and Japanese adult epilepsy patients with uncontrolled partial-onset (focal) seizures (POS) with or without secondary generalization. The study met its primary endpoint for the change in POS frequency per 28 days from baseline to maintenance in the lacosamide 200 mg/day and 400 mg/day. The proportions of patients with at least a 50% reduction in POS frequency during maintenance for lacosamide were statistically significant when compared to placebo. In addition, during the maintenance period a greater proportion of seizure free patients was observed in the lacosamide groups versus placebo. The observed adverse events were similar to those reported in previous lacosamide studies and post marketing surveys.

When marketing authorization is obtained, 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 concluded by the companies in November 2014.

Daiichi Sankyo and UCB Japan hope to 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 Epilepsy

Epilepsy is a disease of the brain that affects approximately 65 million people worldwide. It is a disease of the brain defined by any of the following conditions: (1) at least 2 unprovoked (or reflex) seizures occurring >24h apart; (2) 1 unprovoked (or reflex) seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after 2 unprovoked seizures occurring over the next 10 years; or (3) diagnosis of an epilepsy syndrome. Epilepsy can occur at any age regardless of gender. The incidence of epilepsy varies depending on the age.

## About UCB in 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 supernetworks 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

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# 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 (<u>www.ucb.com</u>) 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).

Established in 1988, UCB Japan markets a number of products including the allergic disease treatment Zyrtec<sup>®</sup> Tablets (cetirizine). The anti-epileptic drug E Keppra<sup>®</sup> (levetiracetam), which was launched in September 2010 and the TNF-a inhibitor Cimzia<sup>®</sup>, 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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