Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

Press Release

FINAL 8-31-17

Daiichi Sankyo Announces Positive Top-line Results from Phase 3 Clinical Trial Evaluating Mirogabalin in Diabetic Peripheral Neuropathic Pain

BASKING RIDGE, NJ and TOKYO – (August 31, 2017) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced positive top-line results from REDUCER (an Asian, phase 3, multicenter, **R**andomiz**E**d, **D**ouble-blind, placebo-controlled 14-week st**U**dy of mirogabalin in patients with diabeti**C** p**E**ripheral neu**R**opathic pain, followed by a 52-week open-label extension).

In the REDUCER clinical trial, mirogabalin demonstrated statistically significant reduction compared to placebo in the primary endpoint, change in weekly average daily pain score (ADPS) from baseline to Week 14. Preliminary and ongoing analyses indicated no significant safety concerns in the REDUCER trial. The REDUCER trial was followed by a 52-week open-label extension at approximately 200 centers in Japan, Taiwan, South Korea and Malaysia.

"The top-line results from the REDUCER trial provide us with important data on the clinical profile of mirogabalin in patients with diabetic peripheral neuropathic pain," said Marielle Cohard-Radice, MD, Executive Vice President, Global Head of Development, Daiichi Sankyo, Inc. "These results, along with the positive data from the NEUCOURSE trial in post-herpetic neuralgia, support mirogabalin's potential use in specific pain syndromes and our path forward for bringing this innovative medicine to patients who need relief from pain."

The primary objective of the 14-week REDUCER trial was to evaluate the efficacy of mirogabalin by comparing the change in the ADPS from baseline to Week 14 in patients receiving 10 mg or 15 mg of mirogabalin twice-daily versus placebo. Weekly ADPS is based on daily pain scores reported by the patient that best describes his or her pain over the previous 24 hours. Secondary objectives in the REDUCER trial included a comparison of the change in ADPS from baseline to Week 14 in patients receiving mirogabalin 15 mg once-daily versus placebo, as well as a comparison of the proportion of

patients by treatment group with greater than or equal to 30 and 50 reductions in ADPS from baseline to Week 14.

The REDUCER trial is an integral component of Daiichi Sankyo's global clinical development program for mirogabalin in neuropathic pain, also inclusive of the NEUCOURSE trial. Top-line results from the NEUCOURSE trial were announced in June 2017. Further results from the REDUCER trial will be disclosed in upcoming scientific forums.

About the REDUCER Phase 3 Clinical Study for Mirogabalin

REDUCER is an Asian, phase 3, multicenter, randomized, double-blind, placebo-controlled 14-week clinical trial of mirogabalin involving 750 patients aged 20 years or older with diabetic peripheral neuropathic pain. The trial was followed by a 52-week open-label extension phase at approximately 200 centers in Japan, Taiwan, South Korea and Malaysia. Patients were randomized into one of four arms (mirogabalin 15 mg once-daily, mirogabalin 10 mg twice-daily, mirogabalin 15 mg twice-daily or placebo) at the ratio of 2:1:1:1, respectively.

About Diabetic Peripheral Neuropathic Pain

Diabetic peripheral neuropathy is one of the most common long-term complications of diabetes.[1] Symptoms include sharp pains or increased sensitivity, numbness, loss of balance and coordination, tingling, burning or prickling sensations, which typically worsen at night.[1] Up to 50 percent of people with diabetes have peripheral neuropathy[2] and it is estimated that between 11 and 26 percent of people with diabetes experience diabetic peripheral neuropathic pain.[3,4,5,6] However, diabetic peripheral neuropathic pain is often undertreated and underreported.[2]

About the Global Clinical Development Program for Mirogabalin

The global phase 3 clinical development program for mirogabalin consists of several phase 3 clinical trials, including NEUCOURSE (post-herpetic neuralgia), REDUCER (diabetic peripheral neuropathic pain) and ALDAY (pain associated with fibromyalgia). Upon completion of these phase 3 trials, more than 6,000 patients will have participated in the mirogabalin clinical development program. The results from the global clinical development program will serve as the basis for potential regulatory submissions in various countries.

About Mirogabalin

Mirogabalin is an oral therapy that preferentially and selectively binds to the α2δ-1 (alpha-2 delta-1) subunit of calcium channels widely found in the nervous system in areas that mediate pain transmission and processing.[7] Mirogabalin has a unique binding profile and long duration of action.[8]

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.

Global and U.S. Contact
Alyssa Dargento
Daiichi Sankyo, Inc.
adargento@dsi.com
+1 908-992-6632 (office)

Japan Contact
Koji Ogiwara
Daiichi Sankyo Co., Ltd.
+81-3-6225-1126 (office)

Forward-looking statements

This press release contains forward-looking statements and information about future developments in the sector, and the legal and business conditions of DAIICHI SANKYO Co., Ltd. Such forward-looking statements are uncertain and are subject at all times to the risks of change, particularly to the usual risks faced by a global pharmaceutical company, including the impact of the prices for products and raw materials, medication safety, changes in exchange rates, government regulations, employee relations, taxes, political instability and terrorism as well as the results of independent demands and governmental inquiries that affect the affairs of the company. All forward-looking statements contained in this release hold true as of the date of publication. They do not represent any guarantee of future performance. Actual

events and developments could differ materially from the forward-looking statements that are explicitly expressed or implied in these statements. DAIICHI SANKYO Co., Ltd. assume no responsibility for the updating of such forward-looking statements about future developments of the sector, legal and business conditions and the company.

---

[1] National Diabetes Information Clearinghouse. Diabetic Neuropathies: The Nerve Damage of Diabetes. NIH Publication No. 09-3185. February 2009.

[2] Boulton, A. Management of Diabetic Peripheral Neuropathy. Clinical Diabetes. 2005; 25(1): 9-15.

[3] Sadosky A et al. A review of the epidemiology of painful diabetic peripheral neuropathy, postherpetic neuralgia, and less commonly studied neuropathic pain conditions. Pain Pract. 2008;8(1):45-56.

[4] Van Acker K, et al. Prevalence and impact on quality of life of peripheral neuropathy with or without neuropathic pain in type 1 and type 2 diabetic patients attending hospital outpatients clinics. Diabetes Metab. 2009;35(3):206-213.

[5] Abbott CA et al. Prevalence and characteristics of painful diabetic neuropathy in a large community-based diabetic population in the U.K. Diabetes Care. 2011;34(10):2220-2224.

[6] Tsuji M et al. Painful diabetic neuropathy in Japanese diabetic patients is common but underrecognized. Pain Res Treat. 2013;2013:318352.

[7] Yokoyama T et al. Pharmacological, pharmacokinetics and safety profiles of DS-5565 a novel α2δ ligand. Poster presented at: World Congress of Neurology; September 21–26, 2013; Vienna, Austria.

[8] Yokoyama T et al. J Neurol Sci. 2013;333:e535.