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Press Release

Daiichi Sankyo Announces Top-line Results from Phase 3 Global Clinical Development Program Evaluating Mirogabalin in Pain Syndromes

BASKING RIDGE, NJ and TOKYO – (June 30, 2017) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced top-line results from NEUCOURSE, a phase 3 clinical trial in patients with post-herpetic neuralgia, and the ALDAY phase 3 clinical trials in patients with fibromyalgia. The NEUCOURSE and ALDAY clinical trials are integral aspects of Daiichi Sankyo's broader global clinical development program for mirogabalin, evaluating its use in pain syndromes including post-herpetic neuralgia, fibromyalgia and diabetic peripheral neuropathic pain.

In NEUCOURSE, a single phase 3, double-blind, placebo-controlled, 14-week study evaluating mirogabalin in Asian patients with post-herpetic neuralgia, mirogabalin met the primary efficacy endpoint by demonstrating a statistically significant reduction in the weekly average daily pain score (ADPS) from baseline to Week 14.

The primary objective of the NEUCOURSE study was to evaluate the efficacy of mirogabalin 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. Key secondary objectives included a comparison of the change in ADPS from baseline to Week 14 in patients receiving mirogabalin 15 mg once-daily versus placebo, and a comparison of the proportion of patients with greater than or equal to 30 percent and greater than or equal to 50 percent reduction from baseline to Week 14 in ADPS receiving each dose of mirogabalin versus placebo. Patients who completed the double-blind phase were eligible to participate in the open-label extension phase, which explored the long-term safety and efficacy of mirogabalin in patients with post-herpetic neuralgia. Several additional secondary and exploratory objectives were also evaluated.

In the three, 13-week, double-blind, global, phase 3 ALDAY clinical trials evaluating mirogabalin for the treatment of pain associated with fibromyalgia, mirogabalin did not meet the primary efficacy endpoint to

demonstrate a statistically significant reduction in the weekly average of worst daily pain score from baseline to Week 13.

The primary objective for each of the ALDAY clinical trials was to evaluate the efficacy of mirogabalin by comparing changes in patients' weekly average of worst daily pain score from baseline to Week 13 in those receiving either mirogabalin 15 mg once-daily or mirogabalin 15 mg twice-daily versus placebo. Weekly average of worst daily pain score is based on the daily pain scores reported by the patient that best describes his or her worst pain over the previous 24 hours. Key secondary objectives of the ALDAY trials included a comparison of the proportion of patients with greater than or equal to 30 percent and greater than or equal to 50 percent reduction from baseline to Week 13 in weekly average of worst daily pain score receiving either dose of mirogabalin versus placebo. Several additional secondary and exploratory objectives were also evaluated.

"The NEUCOURSE and ALDAY results provide us with important data and insights regarding the clinical profile of mirogabalin in specific pain populations," said Marielle Cohard-Radice, MD, Executive Vice President, Global Head of Development, Daiichi Sankyo, Inc. "Daiichi Sankyo is committed to bringing innovative medicines to patients who need relief from pain, and we will continue to study mirogabalin and its potential use in pain syndromes as part of our ongoing global clinical development program."

Preliminary and ongoing analyses indicated no unexpected safety concerns in the NEUCOURSE or ALDAY clinical trials. Full results from the trials will be disclosed in upcoming scientific mediums.

About the NEUCOURSE Phase 3 Clinical Study for Mirogabalin

NEUCOURSE is an Asian, phase 3, multicenter, randomized, double-blind, placebo-controlled, 14-week study of mirogabalin involving 765 post-herpetic neuralgia patients aged 20 years or older across 200 centers in Japan, Taiwan, Korea, Singapore, Malaysia and Thailand. The double-blind phase of the study was followed by a one-year, open-label extension phase.

About the ALDAY Phase 3 Clinical Trials for Mirogabalin

ALDAY is a global, phase 3, multicenter, randomized, double-blind, placebo- and active-controlled, 13-week evaluation of mirogabalin for fibromyalgia in three identical studies involving over 3,600 patients (more than 1,200 patients per study), aged 18 years or older. These studies were conducted in about 300 centers throughout North America, South America, Eastern Europe, Western Europe and the Asia Pacific

region. A separate open-label study, lasting up to one year, of about 2,000 patients that included subjects from any of the three double-blind studies (roll over) or subjects enrolled de novo (newly enrolled), was conducted and is now complete. An additional study in patients with fibromyalgia who have renal impairment is ongoing.

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 on calcium channels widely found in the nervous system in areas that mediate pain transmission and processing.[1] Mirogabalin has a unique binding profile and long duration of action.[2]

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