Press Release

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Daiichi Sankyo Announces Positive Top-line Results from Phase 3 Study in Japan of Esaxerenone for Treatment of Essential Hypertension

Tokyo, Japan（September 25, 2017）– Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the primary endpoint has been achieved from ESAX-HTN study (Phase 3 pivotal study of non-steroidal, selective novel mineralocorticoid receptor (MR) blocker, esaxerenone (INN; code name: CS-3150), for patients with essential hypertension in Japan.

ESAX-HTN study is a double blind study of esaxerenone to evaluate efficacy and safety compared to eplerenone in patients with essential hypertension in Japan. Preliminary and ongoing analyses indicated no significant safety concerns in the ESAX-HTN study. The detailed study results will be disclosed at a future scientific meeting.

In March 2006, Daiichi Sankyo and Exelixis entered into a research collaboration agreement to discover, develop and commercialize novel therapies targeted for MR. Under the terms of the agreement, Daiichi Sankyo has exclusive development, manufacturing and commercialization rights for the compounds worldwide.

Esaxerenone is one of the in-licensed compounds identified during the research collaboration with Exelixis, and has subsequently been developed by Daiichi Sankyo.

About ESAX-HTN

The Phase 3 pivotal study, ESAX-HTN is, a randomized, double-blind, 3-arm, parallel group comparison study with eplerenone as active control in patients with essential hypertension in Japan. The primary

endpoint is sitting systolic blood pressure (SBP) / diastolic blood pressure (DBP) change from baseline after 12-week treatment, and the secondary endpoint is mean 24 hour SBP/DBP change from baseline after 12-week treatment. 1,001 patients were randomized at 44 clinical sites in Japan. Additional information on the study is available on www.clinicaltrials.gov.

About Hypertension

From the Japan National Health and Nutrition Survey 2012, there are estimated to be about 43 million patients with hypertension, which accounts for 60% male adults and 45% female adults over 30 years old in the general population in Japan[*1]. Only 30% of males and 40% of females with hypertension treated with antihypertensive drug medications achieve blood pressure goal (lower than 140/90mmHg in SBP/DBP respectively). Hypertension is one of the major risk factors for cardiovascular disease (ex. stroke, coronary heart disease) and raises risks of chronic kidney disease (CKD) and end-stage renal disease (ESRD) [*1].

Essential hypertension is the major form of hypertension and is the result of heterogeneous factors like genetics and lifestyle habits, while secondary hypertension is hypertension with identified underlying disease factors. Essential hypertension is the most common form of hypertension, accounting for 90% of hypertensive patients[*1].

About Esaxerenone (CS-3150) for hypertention

Esaxerenone is an orally administered, non steroidal, selective blocker of MR. Binding of aldosterone to MR plays a central role in the regulation of plasma sodium (Na+), extracellular potassium (K+) and arterial blood pressure by acting on the collecting ducts in nephrons. In the Phase 2, double blind, placebo-controlled dose finding study with essential hypertension patients in Japan, 2.5mg/day and 5mg/day of esaxerenone showed significant reduction compared to placebo in sitting SBP/DBP[*2].As recently reported, aldosterone is regarded as a potent mediator of organ damage[*3·4]. Esaxerenone may have a role in preventing these organ damaging effects.

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 Exelixis

Founded in 1994, Exelixis, Inc. (Nasdaq: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model genetic systems, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. We discovered our lead compounds, cabozantinib and cobimetinib, and advanced them into clinical development before entering into partnerships with leading biopharmaceutical companies in our efforts to bring them to patients globally. With growing revenues from the three resulting commercialized products – CABOMETYX®, COMETRIQ®, and COTELLIC® – we are reinvesting in our business to maximize the potential of our pipeline, which we intend to supplement with targeted business development activities and internal drug discovery, all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. For more information about Exelixis, please visit www.exelixis.com or follow @ExelixisInc on Twitter.

References

*1 The Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2014). Hypertens Res. 2014; 37: 253-392.

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