Press Release

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Daiichi Sankyo Announces NDA submission in Japan of Esaxerenone for Treatment of Hypertension

Tokyo, Japan（February 27, 2018）– Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced the NDA submission in Japan of esaxerenone (INN; code name: CS-3150), a non-steroidal selective novel mineralocorticoid receptor (MR) blocker for the treatment of hypertension.

This submission is based on the results of phase 3 studies including the ESAX-HTN study in patients with essential hypertension in Japan.

Daiichi Sankyo expects esaxerenone to benefit patients and healthcare professionals in Japan by providing a new therapeutic option for the treatment of hypertension.

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]. 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]. Nevertheless, only 30% of males and 40% of females with hypertension treated with antihypertensive medications achieve their blood pressure goal (lower than 140/90mmHg in SBP/DBP respectively).

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

About Esaxerenone (CS-3150)

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

Esaxerenone is an orally administered, non-steroidal, selective blocker of MR. Excess MR activation, elicited by aldosterone production triggered by the renin angiotensin system, leads to reabsorption of urinary sodium (Na+) and water by the collecting ducts in nephrons, resulting in arterial blood pressure elevation. Esaxerenone blocks MR activation and as a consequence exerts an antihypertensive effect. As recently reported, activation of MR by aldosterone or other mediators is also regarded as a potent mediator of organ damage in heart, blood vessel and kidney[*2,3]. Esaxerenone may therefore demonstrate an organ protective effect. The phase 3 pivotal study (ESAX-DN study) has been on-going in Patients with Diabetic Nephropathy in Japan.

About ESAX-HTN study

ESAX-HTN is, a 3-arm, randomized, double-blind, and parallel group comparison phase 3 study to evaluate efficacy and safety compared to 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. 1,001 patients were randomized at 44 clinical sites in Japan. Esaxerenone 2.5mg/day showed a non-inferior antihypertensive effect to eplerenone 50mg/day in essential hypertension. There was a dose proportional antihypertensive effect between esaxerenone 2.5mg/day and 5mg/day. There were no significant safety concerns in the ESAX-HTN study. Detailed study results will be disclosed at a future scientific meeting.

(Additional information on the study is available on www.clinicaltrials.gov.).

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 these medicines to patients globally. We are steadfast in our commitment to prudently reinvest in our business to maximize the potential of our pipeline. We intend to supplement our existing therapeutic assets 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. Exelixis recently earned a spot on Deloitte's Technology Fast 500 list, a yearly award program honoring the 500 fastest-growing companies over the past four years. 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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