For Immediate Release

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Daiichi Sankyo Initiates Phase 3 study of CS-3150, a Novel Mineralocorticoid Receptor Antagonist for Treatment of Essential Hypertension

Tokyo, Japan（September 27, 2016）– Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has initiated a Phase 3 pivotal study of CS-3150 (esaxerenone (r-INN)), its non-steroidal, selective novel mineralocorticoid receptor (MR) antagonist, for patients in Japan with essential hypertension.

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

CS-3150 is one of the in-licensed compounds identified during the research collaboration with Exelixis, and has subsequently been developed by Daiichi Sankyo.

About the ESAX-HTN Phase 3 Pivotal Trial

ESAX-HTN is a phase 3 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 SBP/DBP change from baseline after 12-week treatment, and the secondary endpoint is mean 24hr SBP/DBP change from baseline after 12-week treatment. Nine hundred and thirty (930) patients are planned to be enrolled at approximately 40 clinical sites in Japan. Additional information on the study is available at www.clinicaltrials.gov.

About Hypertension

From the Japan National Health and Nutrition Survey 2012, there is estimated to be about 43 million patients with hypertension, which accounts for 60% of male adults and 45% of female adults over 30 years old in the general population of Japan[1)]. Only 30% of males and 40% of females who have hypertension and are being treated with antihypertensive medications achieved the 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 most common form of hypertension and has heterogenetic factors like genetics and lifestyle habits, while secondary hypertension is associated with underlying disease factors. Essential hypertension is the most common hypertension, affecting 90% of hypertensive patients[1)].

About CS-3150

CS-3150 (esaxerenone (r-INN)) is an orally administered, non-steroidal, selective inhibitor of the MR. The binding of aldosterone to the 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. As recently reported, aldosterone is regarded as a potent mediator of organ damage[2),3)]. CS-3150 may have a role in preventing these organ damaging effects. CS-3150 is currently in development in hypertension and diabetic nephropathy in Japan.

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 16,000 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

Exelixis, Inc. (NASDAQ: EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Since its founding in 1994, three medicines discovered at Exelixis have progressed through clinical development to receive regulatory approval. Currently, Exelixis is focused on advancing cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors, which has shown clinical anti-tumor activity in more than 20 forms of cancer and is the subject of a broad clinical development program. Two separate formulations of cabozantinib have received regulatory approval to treat certain forms of kidney and thyroid cancer and are marketed for those purposes as CABOMETYX™ tablets (U.S.) and COMETRIQ® capsules (U.S. and EU), respectively. Another Exelixis-discovered compound, COTELLIC® (cobimetinib), a selective inhibitor of MEK, has been approved in major territories including the United States and European Union, and is being evaluated for further potential indications by Roche and Genentech (a member of the Roche Group) under a collaboration with Exelixis. For more information on 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 Research* 2014; 37: 253-392.

2）Funder JW. The role of aldosterone and mineralocorticoid receptors in cardiovascular disease. Am J Cardiovasc Drugs. 2007;7(3):151-7.

3）Rafiq K, Hitomi H, Nakano D, Nishiyama A. et al., Pathophysiological roles of aldosterone and mineralocorticoid receptor in the kidney. J Pharmacol Sci. 2011;115(1):1-7