Press Release

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Daiichi Sankyo Initiates Pivotal Phase 3 study in Japan of Esaxerenone in Patients with Diabetic Nephropathy

Tokyo, Japan（September 25, 2017） – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has initiated ESAX-DN, a Phase 3 pivotal study of esaxerenone (INN) (Code name:CS-3150), a non-steroidal, selective novel mineralocorticoid receptor (MR) blocker, for patients in Japan with diabetic nephropathy.

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 the ESAX-DN Phase 3 Pivotal Trial

ESAX-DN is a phase 3 randomized, double-blind, 2-arm, parallel group comparison study with placebo in patients with type 2 diabetes with microalbuminuria who are taking an angiotensin II receptor blocker (ARB) or an angiotensin converting enzyme (ACE) inhibitor in Japan. The primary endpoint is rate of remission to normoalbuminuria after 52-week treatment, and the secondary endpoints are change rate in urinary albumin creatinine ratio (UACR) and estimated glomerular filtration rate (eGFR).Four hundred (400) patients are planned to be enrolled at approximately 130 clinical sites in Japan. Additional information on the study is available at http://www.clinicaltrials.jp/user/showCteDetailE.jsp?japicId=JapicCTI-173695.

About Diabetic Nephropathy

Diabetic nephropathy is one of the most significant long-term complications in terms of morbidity and mortality for individual patients with diabetes. In Japan, approximately 10 million people, or 12.1 % of the population, are estimated to have diabetes, with a growing incidence. Approximately 50% of all type 2 diabetics will develop evidence of diabetic nephropathy [*1]. It is the leading course of dialysis (43.7%, 2015) in Japan [*2].

Multifactorial intensive therapy, including control of blood glucose, lipid, and blood pressure and using ARB or ACE inhibitor are recommended in the several treatment guidelines for suppressing the onset and progression of early diabetic nephropathy [*3·4·5]. However, these traditional therapies are suboptimal and there is a clear, unmet need for additional treatments.[*6]

The progression to advanced stages of diabetic nephropathy is associated with increased risk of dialysis and cardiovascular events. The effect of medication on the suppression of diabetic nephropathy at the advanced stage is not clear. In order to diminish the deterioration of kidney function, it would be desirable to promote remission to normoalbuminuria in diabetic nephropathy in early stages of the disease. [*7·8]

About Esaxerenone for diabetic nephropathy (CS-3150)

Esaxerenone is an orally administered, non-steroidal, selective blocker of MR. As recently reported, aldosterone is regarded as a potent mediator of organ damage. Esaxerenone may have a role in preventing these organ damaging effects. In Phase 2 multicenter, randomized, double-blind, placebo-controlled, study, esaxerenone 1.25, 2.5, and 5 mg/day on top of ARB or ACE inhibitor for 12 weeks significantly reduced UACR compared to placebo in type 2 diabetic patients with microalbuminuria [*9].

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

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