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Press Release

Daiichi-Sankyo

U.S. FDA Cardiovascular and Renal Drugs Advisory Committee Makes Recommendation on Daiichi Sankyo's Once-Daily SAVAYSA™ (edoxaban) for the Reduction in Risk of Stroke and Systemic Embolic Events in Patients with Non-Valvular Atrial Fibrillation

- *Committee votes 9 to 1 to recommend approval of once-daily SAVAYSA for the reduction in risk of stroke and systemic embolic events (SEE) in patients with non-valvular atrial fibrillation (NVAF)*

- *Daiichi Sankyo to work with the FDA during continued review of its New Drug Application*

Tokyo, Japan, October 31, 2014 – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the U.S. Food and Drug Administration's (FDA) Cardiovascular and Renal Drugs Advisory Committee voted 9 to 1 to recommend approval of once-daily SAVAYSA™ (edoxaban) 60 mg dosing regimen for the reduction in risk of stroke and systemic embolic events (SEE) in patients with non-valvular atrial fibrillation (NVAF). Members of the committee also provided their opinions on the use of SAVAYSA.

"We are confident that the outcomes and robustness of the ENGAGE AF-TIMI 48 study fully support the approval in the U.S. of the 60 mg dosing regimen of SAVAYSA for patients with NVAF, with a dose reduction to 30 mg in selected patients," said Glenn Gormley, MD, PhD, Senior Executive Officer and Global Head of R&D, Daiichi Sankyo Company, Limited and Executive Chairman and President, Daiichi Sankyo, Inc. "We will continue to work with the FDA as it completes its review of our New Drug Application for SAVAYSA for the prevention of stroke and SEE in patients with atrial fibrillation."

The FDA regularly seeks the advice of its advisory committees as it reviews New Drug Applications, although it is not bound to follow the recommendations.

The recommendations were provided after review of the ENGAGE AF-TIMI 48 study results, which were previously communicated at the 2013 American Heart Association Scientific Sessions. The data demonstrated that once-daily edoxaban met the primary efficacy endpoint of non-inferiority compared

to warfarin for the reduction in risk of stroke and SEE in patients with NVAF, and demonstrated significantly less major bleeding compared to warfarin, achieving superiority for the principal safety endpoint of major bleeding.[1] Daiichi Sankyo is currently seeking approval from the FDA for the 60 mg dosing regimen of edoxaban (with a dose reduction to 30 mg for patients with known factors such as renal impairment, low body weight or concomitant use of certain P-glycoprotein inhibitors that can potentially increase the risk of bleeding due to expected higher edoxaban exposure) for the reduction in risk of stroke and SEE in patients with NVAF. Daiichi Sankyo is also seeking approval of edoxaban for the treatment and prevention of recurrence of symptomatic venous thromboembolism (VTE) based on the results from the Hokusai-VTE study, which is the single largest comparative trial of a novel oral anticoagulant in this patient population.

About Atrial Fibrillation

Atrial Fibrillation (AF) is a condition in which the heartbeat is rapid and irregular, and can potentially lead to a stroke. AF is a common condition, affecting approximately 2.3-3.4% of people in developed nations.[2] AF affects approximately 6 million people in the EU,[3] approximately 6.1 million people in the U.S.,[4] approximately 1.5 million people in Brazil,[5] and more than 800,000 people in Japan.[6] Stroke due to all causes is the second most common cause of death worldwide, responsible for approximately 6.2 million deaths each year.[7] Compared to those without AF, people with the arrhythmia have a 3-5 times higher risk of stroke.[2] Strokes due to AF are nearly twice as likely to be fatal than strokes in patients without AF at 30 days and have poorer prognosis than non-AF related strokes, with a 50% increased risk of remaining disabled at three months.[8,9]

About Edoxaban

Edoxaban is an investigational, oral, once-daily anticoagulant that specifically inhibits factor Xa, which is an important factor in the coagulation system that leads to blood clotting.[10] The global edoxaban clinical trial program includes two phase 3 clinical studies, Hokusai-VTE and ENGAGE AF-TIMI 48 (**E**ffective a**N**ticoa**G**ulation with factor x**A** next **GE**neration in **A**trial **F**ibrillation), which included nearly 30,000 patients combined. The results from these trials form the basis of regulatory filings for edoxaban for symptomatic venous thromboembolism (VTE) in patients with deep vein thrombosis and/or pulmonary embolism, and for the prevention of stroke in NVAF, respectively.[1,11] Edoxaban is currently under regulatory review in the U.S. and EU for these indications.

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On September 26, 2014, Daiichi Sankyo announced that it received approval from the Ministry of Health, Labour and Welfare in Japan for LIXIANA® (JAN: Edoxaban Tosilate Hydrate, INN: edoxaban) for the prevention of ischemic stroke and systemic embolism in patients with NVAF and for the treatment and recurrence prevention of venous thromboembolism (VTE) [deep vein thrombosis (DVT) and pulmonary thromboembolism].[12]

Edoxaban was approved in Japan in April 2011, for the prevention of VTE after major orthopedic surgery and was launched in July 2011.[13] Elsewhere, including Europe and the U.S., edoxaban has not been approved in any indication. SAVAYSA is the proposed brand name for edoxaban if approved for marketing in the U.S.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, dyslipidemia and bacterial infections used by patients around the world, the Group has also launched treatments for thrombotic disorders and is building new product franchises. Furthermore, Daiichi Sankyo research and development is focused on bringing forth novel therapies in oncology and cardiovascular-metabolic diseases, including biologics. The Daiichi Sankyo Group has created a “Hybrid Business Model,” to respond to market and customer diversity and optimize growth opportunities across the value chain. 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.

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