

For Immediate Release

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**Daiichi Sankyo Initiates Phase 3 ENSURE-AF Study, Investigating Once-Daily Edoxaban in Patients
with Atrial Fibrillation Undergoing Cardioversion**

Tokyo, Japan(April 1, 2014) - Attached is the press release, which was issued on March 31, 2014.

Press Release

Daiichi Sankyo Initiates Phase 3 ENSURE-AF Study, Investigating Once-Daily Edoxaban in Patients with Atrial Fibrillation Undergoing Cardioversion

First patient enrolled in largest planned phase 3 study evaluating a novel oral anticoagulant in non-valvular atrial fibrillation patients undergoing electrical cardioversion

Parsippany, NJ, March 31, 2014 – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has started enrolling patients into the ENSURE-AF multinational phase 3 study, which will evaluate the efficacy and safety of its investigational oral, once-daily direct factor Xa-inhibitor edoxaban compared to enoxaparin/warfarin for the prevention of stroke and other blood clot complications in patients with non-valvular atrial fibrillation (NVAF) undergoing electrical cardioversion (low-energy shocks to trigger normal heart rhythm).^{1,2} More than 2,200 patients are expected to be enrolled in ENSURE-AF at approximately 250 clinical sites across North America and Europe.¹

“Due to the risk of thromboembolism, clinical guidelines recommend anticoagulation before and after cardioversion in patients with atrial fibrillation,” said Andreas Goette, MD, Chief Physician, St. Vincenz-Hospital Paderborn, Germany, Department of Cardiology and Intensive Care Medicine and member of the European Heart Rhythm Association’s International Affairs Committee with responsibility for Japan.^{3,4} “This trial will provide us with insights on whether edoxaban can be a viable treatment option for non-valvular atrial fibrillation patients undergoing cardioversion.”¹

“This is a very exciting study as this will be the largest planned clinical trial to evaluate a novel oral anticoagulant with the current standard of care in patients undergoing cardioversion” said Gregory YH Lip, Professor of Cardiovascular Medicine, University of Birmingham, UK. “The novel oral anticoagulants offer the possibility of efficacy, safety and convenience for the peri-cardioversion management of patients with atrial fibrillation.”

About ENSURE-AF

ENSURE-AF is a **P**rospective, **R**andomized, **O**pen-Label, **B**linded **E**ndpoint evaluation (PROBE), parallel group study, evaluating the efficacy and safety of once-daily edoxaban for the prevention of stroke, systemic embolic event, myocardial infarction and cardiovascular mortality versus enoxaparin/warfarin in patients with NVAF undergoing electrical cardioversion. More than 2,200 NVAF pa-

tients undergoing electrical cardioversion are expected to be enrolled at approximately 250 clinical sites across North America and Europe. Patients will be randomized to receive edoxaban 60 mg (or a patient specific dose of edoxaban 30 mg for patients with renal impairment or low body weight or p-glycoprotein inhibitor use) or enoxaparin/warfarin for 28-49 days.¹

For more information please visit: <http://clinicaltrials.gov/show/NCT02072434>.

About Atrial Fibrillation and Cardioversion

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.⁵ Stroke is the second most common cause of death worldwide, responsible for approximately 6.2 million deaths each year.⁶ Compared to those without AF, people with the arrhythmia have a 3-5 times higher risk of stroke.⁵ Strokes due to AF are nearly twice as likely to be fatal than strokes in patients without AF at 30 days⁷ and have poorer prognosis than non-AF related strokes, with a 50% increased risk of remaining disabled at three months.⁸ Cardioversion is a procedure that can restore a fast or irregular heartbeat to a normal rhythm, but is associated with a risk of thromboembolic events, including stroke, in patients who do not receive anticoagulation therapy.^{2,9}

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 (Effective aNticoagulation with factor xA next GEneration in Atrial Fibrillation), 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.^{11,12} Edoxaban is currently under regulatory review in Japan, the U.S. and EU for these indications.

Edoxaban is currently approved only in Japan, since April 2011, for the prevention of VTE after major orthopedic surgery, and was launched in July 2011 under the brand name Lixiana[®]. Elsewhere, including Europe and the U.S., edoxaban has not been approved in any indication.¹³

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, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and fo-

cused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will 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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