

## DAIICHI SANKYO COMPLETES ENROLLMENT OF THE EDOXABAN GLOBAL PHASE III ENGAGE AF-TIMI 48 STUDY IN PATIENTS WITH ATRIAL FIBRILLATION

More than 21,000 Patients Enrolled in the Largest Clinical Study with a Factor Xa Inhibitor

**December 2, 2010;Tokyo Japan** – Daiichi Sankyo Company, Limited (TSE: 4568), announced today that it has successfully completed patient enrollment for its Phase III ENGAGE AF-TIMI 48 clinical study of edoxaban, a direct, specific, oral Factor Xa inhibitor that is being investigated in two different dosing regimens given once daily, to prevent the occurrence of strokes and systemic embolic events (SEE) in patients with atrial fibrillation (AF).

An estimated 4.5 million people in Europe, 2.2 million Americans, and more than 800,000 people in Japan suffer from AF.<sup>i,ii,iii</sup> Due to the aging population, the number of patients with AF worldwide is likely to increase 2.5 fold by the year 2050.<sup>iv</sup>

The ENGAGE AF-TIMI 48 study began enrollment in November 2008. It is an eventdriven, randomized, double-blind, double-dummy, parallel group, multi-center, multinational study designed to assess the efficacy and safety of edoxaban compared to the current standard of care, warfarin. Patients in the study are randomized to one of three treatment groups: 30 mg edoxaban once daily, 60 mg edoxaban once daily, or warfarin, a vitamin K antagonist. In addition, edoxaban doses are further adjusted to treat patients with renal impairment and/or low body weight, or those taking strong P-glycoprotein inhibitors. Those randomized to warfarin are dosed once daily to achieve an International Normalized Ratio (INR) between 2.0 and 3.0. "The completion of enrollment for the largest AF outcomes study ever undertaken --ENGAGE AF-TIMI 48 -- marks a key milestone in the development of edoxaban and for Daiichi Sankyo," said Glenn Gormley, MD, PhD, Chief Science Officer & President, Daiichi Sankyo Pharma Development.

This Phase III global AF study, Effective aNticoaGulation with factor xA next GEneration in Atrial Fibrillation (ENGAGE AF-TIMI 48), enrolled 21,107 subjects at nearly 1,400 clinical trial sites located throughout North America, South America, Africa, Asia, Europe and Australia/New Zealand. The primary endpoint of this study is to compare the efficacy of edoxaban to warfarin in the prevention of stroke and SEE. The primary safety assessment is the incidence of major bleeding events.

"As new options to prevent stroke in AF patients become available, it will be important that these treatments eliminate the need for extensive monitoring and dietary modifications," said Elliott Antman, MD, Professor of Medicine, Harvard Medical School, Senior Investigator with the Brigham and Women's Hospital-based TIMI Study Group. "Based on Phase II study results, edoxaban has shown promise of potentially addressing the needs of patients with AF and the physicians caring for them."

## **About Atrial Fibrillation**

Atrial fibrillation (AF) is an irregular heartbeat that is caused when the upper chambers of the heart (the atria) do not beat regularly and instead quiver erratically. When this happens, blood may stagnate in the atria leading to blood clots. These blood clots can break off and travel through the blood stream to the brain where they can plug the blood vessels, causing a stroke. AF is the most common type of clinically significant arrhythmia.<sup>v</sup>

Patients with AF have five times higher risk of having a stroke than individuals without AF.<sup>vi</sup> These patients also tend to have more serious first strokes than patients without AF, resulting in higher mortality rates and longer hospital stays.<sup>VII</sup>

# About Edoxaban

Edoxaban is a once-daily oral anticoagulant that directly inhibits Factor Xa, an important factor in the coagulation process. Edoxaban may offer physicians a wide therapeutic window to help address patients' unique needs. Daiichi Sankyo is developing edoxaban as a potential new treatment for the prevention of both arterial and venous thromboembolism. Notably, Daiichi Sankyo has more than 25 years experience conducting research in the area of Factor Xa inhibition and was the first company to study these compounds in humans. Edoxaban is being developed solely by Daiichi Sankyo.

# About Daiichi Sankyo

The 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 focused 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 news release may contain forward-looking statements based on current assumptions and forecasts made by Daiichi Sankyo group. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports, which are available on the website at www.daiichisankyo-us.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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i Fuster V et al. "ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation – Executive Summary," *Circulation.* 2006; 114:700-752.

ii American Heart Association. "Atrial Fibrillation," <u>www.americanheart.org/presenter.jhtml?identifier=4451</u>. Last accessed November 24, 2010.

iii Inoue H et al. "Prevalence of Atrial Fibrillation in the General Population of Japan: An Analysis Based on Periodic Health Examination International," *International Journal of Cardiology*. 2009; 137:102–107.

iv Santini M, Ricci RP. "The Worldwide Social Burden of Atrial Fibrillation: What Should Be Done and Where Do We Go," *Journal of Interventional Cardiac Electrophysiology*. 2006; 17:183–188.

v National Heart Lung and Blood Institute. "What is Atrial Fibrillation,"

www.nhlbi.nih.gov/health/dci/Diseases/af/af\_what.html. Last accessed November 24, 2010.

vi Hylek HM et al. "Effect of Intensity of Oral Anticoagulation on Stroke Severity and Mortality in Atrial Fibrillation."

The New England Journal of Medicine. 2003; 349:1019-1026.

vii Jorgensen HS et al. "Acute Stroke with Atrial Fibrillation," Stroke. 1996; 27:1765-1769.