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# DAIICHI SANKYO SUBMITS FIRST NEW DRUG APPLICATION FOR ORAL FACTOR Xa INHIBITOR, EDOXABAN

Innovative Once-Daily Oral Factor Xa Inhibitor Submitted for Approval in Japan

**TOKYO, Japan (April 6, 2010)** – Daiichi Sankyo Company, Limited announced today that it has submitted a New Drug Application to the Ministry of Health, Labor and Welfare in Japan seeking approval of the anticoagulant, edoxaban, for the prevention of venous thromboembolism (VTE) after major orthopedic surgery.

Edoxaban, being developed solely by Daiichi Sankyo, is an oral anticoagulant that directly and specifically inhibits Factor Xa, a clotting factor in the blood. Results from pivotal Phase III studies showed that once-daily oral administration of edoxaban reduced the incidence of VTE in patients undergoing total knee replacement or total hip replacement, and the non-inferiority to injectable enoxaparin sodium was confirmed.

"Upon approval, we believe that edoxaban, with its simple once-daily oral dosing, will be a significant improvement for patients undergoing orthopedic surgery in Japan." said Dr. Kazunori Hirokawa, Head of the R&D Division of Daiichi Sankyo, Co., Ltd

The pivotal Phase III studies conducted to support this first application in Japan – one in knee surgery and the other in hip surgery – were randomized, double-blind, parallel group, multi-center trials comparing a once-daily, 30 mg oral dose of edoxaban to 2,000 IU (20 mg) twice-daily subcutaneous injections of enoxaparin sodium. Treatment was provided for 11 to 14 days in both trials.

The primary efficacy endpoint in both trials was to confirm non-inferiority of edoxaban to enoxaparin sodium for the prevention of asymptomatic and symptomatic deep vein thrombosis and symptomatic pulmonary embolism. The primary safety endpoint in both

trials was to compare the incidence of major and clinically relevant non-major bleeding between edoxaban and enoxaparin sodium groups.

Full trial results will be submitted for presentation and publication in peer-reviewed settings.

### **GLOBAL DEVELOPMENT OF EDOXABAN**

The global clinical development program for edoxaban includes several indications, including the prevention of stroke and systemic embolic events in patients with atrial fibrillation, as well as the acute treatment and long-term secondary prevention of VTE.

"Early phase data show that edoxaban is an innovative anticoagulant with direct, specific and reversible activity on Factor Xa, which is being investigated as a treatment for a variety of medical conditions, such as atrial fibrillation and VTE, as an alternative to current oral and injectable products," said Dr. Hirokawa.

### Global studies include:

- ENGAGE AF-TIMI 48: Investigating once-daily edoxaban versus warfarin in more than 16,500 patients with atrial fibrillation for the prevention of stroke and systemic embolic events. ENGAGE AF-TIMI 48 began enrollment in late 2008.
- HOKUSAI VTE: To date, the largest single trial for the secondary prevention of recurrent VTE in patients with deep vein thrombosis and pulmonary embolism as well as for the acute treatment of VTE. HOKUSAI VTE began enrollment in early 2010.

Both HOKUSAI VTE and ENGAGE AF-TIMI 48 are Phase III, multi-national, randomized, double-blind studies.

### **About Daiichi Sankyo**

In keeping with its vision of becoming a "Global Pharma Innovator," the Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of customers in both developed 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

## 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, DAIICHI SANKYO, Inc., and DAIICHI SANKYO EUROPE GmbH. 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, DAIICHI SANKYO, Inc., and DAIICHI SANKYO EUROPE GmbH 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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