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Press Release

Daiichi Sankyo Completes Enrolment in Hokusai – VTE, investigating once-daily Edoxaban in the Largest Single Phase 3 Study for the Treatment and Prevention of Recurrence of VTE

Edoxaban is an investigational, once daily, novel oral factor Xa inhibitor

Tokyo, Japan, October 25, 2012 – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has completed patient enrolment in the global Hokusai-VTE phase 3 study investigating the once-daily oral factor Xa inhibitor edoxaban for the treatment and prevention of recurrence of venous thromboembolism (VTE) in patients who have had an acute symptomatic deep vein thrombosis (DVT), pulmonary embolism (PE), or both.[1,2]

Hokusai-VTE is the largest single phase 3 clinical study in the treatment and prevention of recurrence of VTE. More than 8,250 patients have been enrolled in the trial from more than 400 clinical sites across 38 countries worldwide.[1,2]

The Hokusai-VTE clinical study has been designed to reflect clinical practice, using a standard heparin lead-in, and providing a flexible treatment duration of three, six or 12 months. Edoxaban 60mg once-daily will be compared to warfarin control therapy (target INR 2-3).[2] This study design is allowing investigators to evaluate patients with a broad range of risks, including patients with moderate or severe conditions of PE and DVT.[1,3,4]

"With its rigorous design and large patient population, Hokusai-VTE marks an important step in the development of the new class of oral anticoagulants, direct factor Xa inhibitors," said Professor Harry Büller, MD, PhD, Professor of Internal Medicine, Chairman of the Department of Vascular Medicine at the Academic Medical Center in Amsterdam, The Netherlands and Chairman of the Hokusai-VTE steering committee. "What sets the Hokusai-VTE study apart from other studies of its kind is that it aims to reflect clinical practice through the flexible treatment duration."

Edoxaban is an investigational once-daily, novel oral anticoagulant that specifically, reversibly and directly inhibits factor Xa, which is an important factor in the coagulation system that leads to blood clotting.[5,6]

"We are very pleased to announce that we have completed patient recruitment for the Hokusai-VTE clinical study, the largest global study of its kind and we expect to see first results during FY 2013," said Glenn Gormley, MD, PhD, Global Head of Research and Development and Senior Executive Officer, Daiichi Sankyo.

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).[1,7]

About Hokusai-VTE

The Hokusai-VTE clinical study is a double-blind, double-dummy, event-driven, multi-national, randomized parallel-group phase 3 clinical study investigating once-daily edoxaban in patients with symptomatic DVT and/or PE compared to warfarin.[1] Hokusai-VTE is the largest single phase 3 clinical study in the treatment and prevention of recurrence of VTE. More than 8,250 patients have been enrolled in more than 400 clinical sites across 38 countries worldwide.[1,2]

This study is named after the famous Japanese artist and painter Katsushika Hokusai.

About Venous Thromboembolism

VTE is the term for the generation of a blood clot within a vein, or the subsequent breaking off of that clot into a pulmonary (lung) artery.[8] DVT and PE are the two sub-types of VTE.[3] DVT is a blood clot found anywhere in the deep veins of the legs, pelvis or arms.[8] PE occurs when part of a clot from within a deep vein detaches and embolises to the lungs lodging in the pulmonary arteries causing a potentially fatal condition.[3,8] PE is often accompanied by DVT and a DVT can develop into a PE suddenly.[3] The ACCP Guidelines recommend that patients with diagnosed VTE are treated for three, six or 12 months (and sometimes even longer) based on the provoking factor and / or their individual risk profile to prevent a second (recurrent) DVT or PE.[3,4]

VTE is a major cause of morbidity and mortality worldwide and the annual incidence of VTE has been estimated at between one to three per 1000 with some age and regional variation.[9] In Europe, more than 750,000 VTE events affect people in six major European countries (France, Germany, Italy, Spain, Sweden and UK) annually, and approximately 370,000 deaths are related to VTE per year in these countries.[10] It is estimated that more than 900,000 fatal and non-fatal VTE events occur in the U.S. annually and approximately 300,000 deaths are related to VTE per year.[11] The prevalence of VTE is predicted to double by 2050.[12] Thirty percent of people with VTE die within one month of diagnosis and about 20% of those with PE experience sudden death.[13]

About Edoxaban

Edoxaban is licensed only in Japan for the prevention of venous thromboembolism (VTE) after major orthopaedic surgery, under the brand name Lixiana®.

Elsewhere, including Europe and the U.S., edoxaban is currently in phase 3 of clinical development and has not been approved yet. Daiichi Sankyo continues to develop edoxaban at a global level as a potential new treatment for the prevention of stroke and systemic embolic events (SEE) in patients with non-valvular atrial fibrillation (AF) and for the treatment and prevention of recurrence of VTE in patients with acute deep vein thrombosis (DVT) and/or pulmonary embolism (PE).

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 infectious diseases, the Group is engaged in the development of innovative treatments for thrombotic disorders and focused on the discovery of novel therapies in the designated priority research areas of oncology and cardiovascular-metabolic therapies.

Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," encompassing innovative pharmaceuticals (new drugs), established pharmaceuticals (generics), vaccines, and OTC products, which will globally 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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Contact

Michaela Paudler-Debus, PhD
Daiichi Sankyo, Co., Ltd.
(Japan)
+81-3-6225-1338 (office)
+81 80 4359 9421 (cell)

Alyssa Dargento
Daiichi Sankyo, Inc.
(U.S.A.)
+ 1-973-944-2913 (office)
+1-973-727-1604 (cell)

Lydia Worms
Daiichi Sankyo Europe
(Europe)
+49 89-78 08 751(office)
+49 176-11780861(cell)

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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