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Daiichi Sankyo

HOKUSAI VTE - Largest Single Phase III Trial for the Treatment and Prevention of Recurrent VTE Started in Europe

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Nuremberg, Germany, February 26, 2010 (ots/PRNewswire) - Edoxaban, a direct oral factor Xa inhibitor, is now being investigated in a second large-scale pivotal phase III trial, HOKUSAI (pronounced hoek-sigh) VTE. This phase III trial is evaluating the safety and efficacy of edoxaban in the treatment and prevention of recurrent thromboembolic events in patients with deep-vein thrombosis (DVT) and/or pulmonary embolism (PE). HOKUSAI VTE[1] is currently the largest single, randomised, multinational phase III trial for treatment and prevention of recurrent venous thromboembolism (VTE), involving approximately 7,500 patients in 450 clinical sites in 40 countries.

"In Europe, VTE affects more than 750,000 people in six major European countries and approximately 370,000 deaths per year are related to VTE in these countries,[2]" said Henri Bounameaux, MD, Professor of Medicine, Director of the Division of Angiology and Hemostasis, Chairman of the Department of Medicine at the University Hospital of Geneva, Switzerland, during a press conference organized by DAIICHI SANKYO EUROPE.

Anticoagulants interfere with the coagulation system resulting in a decreased tendency for the formation of blood clots, and are used to treat and prevent thromboembolic events. Existing anticoagulants like heparins and vitamin K antagonists, although effective, have several limitations. Heparins are injectable agents and therefore less suitable for long-term treatment. Vitamin K antagonists are given orally, but associated with numerous drug-drug and drug-food interactions.

"The current chronic standard treatment of VTE, vitamin K antagonists, requires extensive monitoring and continuous dose adaptation to avoid excessive bleedings and to ensure effective anticoagulation," said Sebastian Schellong, MD, Professor for Internal Medicine, Head of Medical Division 2, Municipal Hospital Friedrichstadt, Dresden, Germany. "Based on the data on edoxaban we have seen so far, it has a predictable pharmacokinetic and dynamic profile that allows for a convenient once-daily dosing that can be kept constant throughout the treatment period."

The data are encouraging for patients and supports edoxaban's potential to significantly improve the management of anticoagulation, while providing effective protection against recurrent thromboembolic events.

"HOKUSAI VTE is intended to show that VTE patients can be treated effectively and safely with the most simple and most convenient dosing regimen among factor Xa inhibitors," said Harry R. Büller, MD, Professor of Internal Medicine, Chairman of the Department for Vascular Medicine at the Academic Medical Center, Amsterdam, The Netherlands and lead investigator for HOKUSAI VTE.

HOKUSAI VTE is an event-driven, double-blind, double-dummy, parallel-group study, which will randomise patients to two different treatment groups. Both groups will receive enoxaparin or unfractionated heparin for at least five and up to 12 days, followed by double-blind warfarin with a target INR of 2-3 or edoxaban 60 mg once-daily. Patients will be treated for up to 12 months in accordance to the standard of care and international guidelines.

The primary efficacy endpoint for HOKUSAI VTE is the recurrence of symptomatic VTE (i.e. the composite of DVT, non-fatal PE, and fatal PE). The primary safety assessment of the trial is the incidence of major and clinically relevant non-major bleeding. The sponsor, DAIICHI SANKYO, expects the study to conclude in 2012.

The HOKUSAI VTE study is named after the famous Japanese artist and painter Katsushika Hokusai (1760-1849) of the former Edo period; "Edo" is the city currently known as Tokyo, the location of the DAIICHI SANKYO global headquarters.

In addition to the HOKUSAI VTE study, an ongoing, multinational, randomised, double blind, phase III study, aims to demonstrate the safety and efficacy profile of edoxaban amongst more than 16,500 patients with atrial fibrillation (ENGAGE AF-TIMI 48) [3].

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References:

[1] Clinicaltrials.gov : NCT00986154, Available at <http://www.clinicaltrials.gov/ct2/show/NCT00986154?term=hokusai&rank=1>. Accessed December 3, 2009.

[2] Cohen AT et al. Venous Thromboembolism (VTE) in Europe. *Thromb Haemost* 2007; 98:756-64.

[3] ClinicalTrials.gov Identifier: NCT00781391

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