



**Daiichi-Sankyo**

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**EMBARGOED UNTIL: February 3, 2010**

**DAIICHI SANKYO INITIATES LARGEST SINGLE, DOUBLE-BLIND, RANDOMIZED,  
PHASE III TRIAL FOR TREATMENT AND PREVENTION OF  
RECURRENT VENOUS THROMBOEMBOLISM**

*First Patient Randomized and Dosed in New Trial with Factor Xa Inhibitor, Edoxaban*

**Tokyo, Japan and Edison, N.J. – February 3, 2010** – Daiichi Sankyo Company, Limited (TSE: 4568), announced today that it has initiated a new large-scale pivotal Phase III trial for edoxaban, its investigational oral Factor Xa inhibitor. This new study, called HOKUSAI (pronounced hoe-koo-sigh) VTE, is evaluating the safety and efficacy of edoxaban in reducing recurrent venous thromboembolic (VTE) complications in patients with deep-vein thrombosis (DVT) and/or pulmonary embolism (PE).

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.<sup>i</sup> In Europe, VTE affects more than 750,000 people in six major European countries (France, Germany, Italy, Spain, Sweden, UK) annually, and approximately 370,000 deaths are related to VTE per year in these countries<sup>ii</sup>.

“The incidence of VTE is predicted to double by 2050,<sup>iii</sup>” said Harry R. Büller, M.D., Professor of Internal Medicine, chairman of the Department for Vascular Medicine at the Academic Medical Center, Amsterdam and chairman of the Steering Committee for HOKUSAI VTE. “Based on what we’ve seen in Phase II and other trials, edoxaban shows promise as an agent to help fulfill the need for treatment options that are safe, effective and more convenient than the current standard of care, which requires extensive monitoring, careful dose adjusting and may have the potential for various drug and food interactions.”

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.

“HOKUSAI VTE is the largest, single Phase III study ever undertaken in the area of VTE, and is our second large-scale edoxaban trial,” said Glenn Gormley, president of Daiichi Sankyo Pharma Development. “Daiichi Sankyo is proud to be advancing the research of Factor Xa inhibitors with edoxaban, which may help prevent deadly clots in various patient populations.”

### **HOKUSAI VTE Study Design**

HOKUSAI VTE is a Phase III multi-center study that will include approximately 7,500 patients in more than 450 clinical sites in approximately 40 countries worldwide. This is an event-driven, randomized, double-blind, double-dummy, parallel-group, multi-center, multi-national study, which will randomize patients to two different treatment groups. Both groups will receive open label enoxaparin or unfractionated heparin for at least five days and up to 12 days, followed by double-blind warfarin 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 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.

### **About Venous Thromboembolism**

Venous thromboembolism (VTE) is the term for the generation of a blood clot and the obstruction of a vein or a pulmonary artery by a blood clot. Deep vein thrombosis (DVT) and pulmonary embolism (PE) are types of VTE. DVT is a blood clot anywhere in the deep veins of the legs or pelvis. PE is caused by a clot that travels to the lungs, lodging in the pulmonary arteries.

### **About Edoxaban**

Edoxaban, the free base of DU-176b, is an oral anticoagulant that directly inhibits Factor Xa, an important factor in the coagulation process. 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.

Daiichi Sankyo is also actively enrolling 16,500 patients in its pivotal Phase III trial for edoxaban in patients with atrial fibrillation. The Phase III study, Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation (ENGAGE AF-TIMI 48), began enrolling patients in late 2008 and is comparing edoxaban with warfarin (target INR 2-3) for the prevention of stroke and systemic embolic events (SEE) among patients with atrial fibrillation.

In Japan, edoxaban is currently being developed for the prevention of VTE in patients after total knee (TKR) and total hip replacement (THR) surgery: results from one pivotal Phase III trial for TKR were announced in late 2009 and a second Phase III trial for THR is ongoing.

### **About Daiichi Sankyo**

A global pharmaceutical innovator, Daiichi Sankyo Co., Ltd., was established in 2005 through the merger of two leading Japanese pharmaceutical companies. This integration created a more robust organization that allows for continuous development of novel drugs that enrich the quality of life for patients around the world. Areas of central focus of Daiichi Sankyo research and development are thrombotic disorders, malignant neoplasm, diabetes mellitus, and autoimmune disorders. Equally important to the company are

hypertension, hyperlipidemia or atherosclerosis and bacterial infections. For more information, visit [www.daiichisankyo.com](http://www.daiichisankyo.com).

**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](http://www.daiichisankyo-us.com) or [www.daiichi-sankyo.eu](http://www.daiichi-sankyo.eu). 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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<sup>i</sup> Heit JA, Cohen AT, Anderson FAJ, on behalf of the VTE Impact Assessment Group. Estimated annual number of incident and recurrent, non-fatal and fatal venous thromboembolism (VTE) events in the US. ASH Annual Meeting Abstracts. 106:910. 2005.

<sup>ii</sup> Cohen AT et al. Venous Thromboembolism (VTE) in Europe. Thromb Haemost 2007; 98:756-64

<sup>iii</sup> Journal of Thrombosis and Haemostasis 2007; Volume 5, Supplement 2: abstract number OC-WE-018, Available at: <http://www.blackwellpublishing.com/isth2009/abstract.asp?id=76605>. Accessed, September 23, 2009