



Daiichi-Sankyo

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EDOXABAN DEMONSTRATES SUPERIOR EFFICACY COMPARED WITH ENOXAPARIN SODIUM IN PREVENTING VTE AFTER TOTAL KNEE REPLACEMENT

TOKYO, Japan (July 12, 2010) – Daiichi Sankyo Company, Limited announced that its investigational once-daily oral, direct factor Xa inhibitor, edoxaban, was shown to be superior to enoxaparin in preventing venous thromboembolic (VTE) events in patients following total knee replacement (TKR), a type of major orthopedic surgery. Results from the Phase III STARS E-3 (Studying Thrombosis After Replacement Surgery) study were presented at the 21st International Congress on Thrombosis (ICT) in Milan, Italy.ⁱ

This multicenter, double-blind, double dummy, centrally randomized trial evaluated the efficacy and safety of edoxaban compared with enoxaparin in patients undergoing TKR in Japan and Taiwan. A total of 716 patients received either 30 mg once-daily oral dose of edoxaban or subcutaneous injection of enoxaparin 2,000 international units (equivalent to 20 mg) twice-daily for 11 to 14 days. The primary efficacy endpoint of the trial was the incidence of symptomatic pulmonary embolism (PE) and symptomatic and asymptomatic deep vein thrombosis (DVT). The primary safety endpoint was the incidence of major bleeding and clinically relevant non-major bleeding.

DVT occurred in 7.4 percent of patients receiving edoxaban once-daily compared with 13.9 percent of patients who received enoxaparin (relative risk reduction of 46.8 percent; $p=0.01$). There were no PE events observed in either treatment group. There was no statistically significant difference in major and clinically relevant non-major bleeding ($p=0.13$). There were no cases of intracranial hemorrhage or death in either treatment group.

Indicators for potential liver damage in both treatment groups were carefully monitored during this trial by measuring bilirubin and serum aminotransferase levels.ⁱⁱ Elevations greater than three times the upper limit of the normal range of serum aminotransferase levels occurred in 1.4 percent of patients taking edoxaban compared with 8.0 percent of those taking enoxaparin.

“The combination of efficacy, tolerability and convenient once-daily oral dosing in this clinical setting further supports the potential role of edoxaban in helping patients and physicians avoiding thrombotic events,” said Dr. Takeshi Fuji, Head of Orthopedic Surgery, Osaka Koseinenkin Hospital. “These results are encouraging as they demonstrate superior efficacy of once-daily edoxaban compared with twice daily subcutaneous enoxaparin, the current standard of care for this patient population.”

In March 2010, Daiichi Sankyo submitted a New Drug Application to the Ministry of Health, Labor and Welfare in Japan seeking approval of edoxaban for the prevention of VTE after major orthopedic surgery.

GLOBAL DEVELOPMENT OF EDOXABAN

The global clinical development program for edoxaban comprises 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. Global studies include:

- **ENGAGE AF-TIMI 48:** Investigates two different doses of once-daily edoxaban versus warfarin in approximately 20,500 patients with atrial fibrillation for the prevention of stroke and systemic embolic events. ENGAGE AF-TIMI 48 began enrollment in late 2008 and is expected to be completed in 2012.
- **HOKUSAI VTE:** To date, the largest single trial for the secondary prevention of recurrent VTE in approximately 7,500 patients with deep vein thrombosis and/or pulmonary embolism as well as for the acute treatment of VTE. HOKUSAI VTE trial enrollment began in early 2010.

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

ABOUT EDOXABAN

Edoxaban is a once-daily 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.

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

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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ⁱT. Fuji et al., Edoxaban versus enoxaparin for thromboprophylaxis after total knee replacement: The STARS E-3 trial 21st International Congress of Thrombosis, July 6 – 9 2010, Milano.

ⁱⁱ Liver Blood Tests. Available at: http://www.medicinenet.com/liver_blood_tests/page2.htm. Accessed June 18, 2010.