



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

TOKYO, Japan (December 8, 2010) – Daiichi Sankyo Company, Limited announced that its investigational once-daily oral, direct factor Xa inhibitor, edoxaban, was shown to be superior to enoxaparin sodium in preventing venous thromboembolic (VTE) events in patients following total hip replacement (THR), a type of major orthopedic surgery. Results from the Phase III STARS J-V (Studying Thrombosis After Replacement Surgery) study were presented at the 52nd Annual Meeting of the American Society of Hematology in Orlando.ⁱ

This multicenter, double-blind, double dummy, centrally randomized trial evaluated the efficacy and safety of edoxaban compared with enoxaparin sodium in patients undergoing THR in Japan. A total of 610 patients received either 30 mg once-daily oral dose of edoxaban or subcutaneous injection of enoxaparin sodium 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 2.4 percent of patients receiving edoxaban once-daily compared with 6.9 percent of patients who received enoxaparin sodium (relative risk reduction of 65.7 percent; $p=0.016$). There were no PE events observed in either treatment group. There was no statistically significant difference in major and clinically relevant non-major bleeding ($p=0.475$). 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 2.6 percent of patients taking edoxaban compared with 10 percent of those taking enoxaparin sodium.

“The medical community in Japan is looking forward to edoxaban as a new treatment for preventing VTE after hip replacement procedures and as more convenient, oral therapeutic option for patients,” said Dr. Takeshi Fuji, Head of Orthopedic Surgery, Osaka Koseinenkin Hospital.

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.

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

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Forward-looking statements

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ⁱT. Fuji et al., Efficacy and Safety of Edoxaban Versus Enoxaparin for the Prevention of Venous Thromboembolism Following Total Hip Arthroplasty: STARS J-V trial, December 4-7 2010, Orlando, Florida.

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