



Daiichi Sankyo Launches LIXIANA[®] (edoxaban), a Direct Oral Factor Xa Inhibitor, in Japan for the Prevention of Venous Thromboembolism after Major Orthopedic Surgery

-- First Direct Oral Factor Xa Inhibitor Available to Japanese Patients --

TOKYO, Japan (July 19, 2011) – Building on its cardiovascular portfolio, Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), is proud to announce the launch of LIXIANA[®] (JAN: Edoxaban Tosilate Hydrate, INN: edoxaban) in Japan. This announcement follows the first marketing approval for edoxaban 15 mg and 30 mg tablets by the Japanese Ministry of Health, Labour and Welfare in April 2011¹, and marks the first time edoxaban is commercially available to patients in any global market.

Edoxaban is a once-daily, oral anticoagulant that specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood. Results from clinical studies supported the approval of edoxaban for the prevention of venous thromboembolism (VTE) in patients with total knee arthroplasty, total hip arthroplasty and hip fracture surgery.

“Today’s launch of edoxaban marks the global debut of the medication, which is an exciting breakthrough for patients who require VTE prevention after major orthopedic surgery,” said Joji Nakayama, President and CEO of Daiichi Sankyo. “Edoxaban demonstrates solid efficacy in clinical trials^{2, 3} in this population of patients. Its predictable pharmacokinetic and pharmacodynamic profile allows for a convenient, once-daily dosing.”

The global clinical development program for edoxaban is focused on several indications, including stroke prevention in atrial fibrillation (AF) patients, and treatment and prevention of recurrent VTE. Edoxaban is currently being assessed in the Phase III ENGAGE AF-TIMI 48 study⁴, an ongoing, multinational, randomized, double-blind trial evaluating the efficacy and safety of edoxaban in preventing stroke and systemic embolic events in patients with AF. More than 21,000 patients with AF in 46 countries are being examined, making this the largest trial in this indication to date. In addition, Daiichi Sankyo is currently enrolling patients in its HOKUSAI VTE study⁵ – the largest single, double-blind, randomized, multinational Phase III study for the treatment and prevention of recurrent VTE, involving approximately 7,500 patients in 450 clinical sites in approximately 40 countries worldwide.

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 such a clot that breaks off and then travels to the lungs, lodging in the pulmonary arteries.

About Edoxaban

Edoxaban is a once-daily oral anticoagulant that directly inhibits Factor Xa, an important factor in the coagulation process. Edoxaban is currently available only in Japan, licensed for the prevention of venous thromboembolism (VTE) in patients undergoing total knee arthroplasty, total hip arthroplasty and hip fracture surgery¹. Daiichi Sankyo continues to develop edoxaban at a global level as a potential new treatment for stroke prevention in atrial fibrillation, and the treatment and prevention of recurrent VTE. 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.

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

References

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