Daiichi Sankyo Receives First Market Approval in Japan for LIXIANAÃ,® (edoxaban), a Direct Oral Factor Xa Inhibitor, for the Prevention of Venous Thromboembolism after Major Or...

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TOKYO, April 22, 2011 /PRNewswire/ -- Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), announced today that the company has received its first marketing approval for LIXIANA® (JAN: Edoxaban Tosilate Hydrate, INN:edoxaban) 15 mg and 30 mg tablets, by the Ministry of Health, Labor and Welfare in Japan.

Edoxaban, which is being developed solely by Daiichi Sankyo, 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.

Commenting on receiving the first national marketing authorization for edoxaban, Joji Nakayama, president and CEO of Daiichi Sankyo, said, "We are pleased to confirm that an exciting milestone has been reached, and we are confident that edoxaban will make a great contribution to VTE prevention after major orthopedic surgery. Daiichi Sankyo also remains committed to exploring the potential for edoxaban in several other indications, and has a robust global clinical trial program."

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 venous thromboembolism. In the ENGAGE AF-TIMI 48 study, an ongoing, multinational, randomized, double-blind, Phase III study, the efficacy and safety of edoxaban in preventing stroke and systemic embolic events in patients with AF are being examined in more than 21,000 patients with AF in 46 countries.(1)

The ENGAGE AF-TIMI 48 study is the largest trial in this indication to date. Also currently ongoing, the HOKUSAI VTE study is the largest single, double-blind, randomized, multinational Phase III study in the treatment and prevention of recurre
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