



Daiichi Sankyo Receives First Market Approval in Japan for LIXIANA[®] (Edoxaban), a Direct Oral Factor Xa Inhibitor, for the Prevention of Venous Thromboembolism after Major Orthopedic Surgery

TOKYO, Japan (April 22, 2011) – 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 VTE. 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 recurrent VTE, involving approximately 7,500 patients in 450 clinical sites in approximately 40 countries.²

Existing anticoagulants such as heparins and vitamin K antagonists, although effective, have several clinical considerations. Heparins are injectable agents and therefore less suitable for long-term treatment. Vitamin K antagonists are given orally, but are associated with numerous drug and food interactions.³ Commenting on the future global potential for edoxaban, Kazunori Hirokawa, Global Head of R&D Unit, Daiichi Sankyo, said, "Based on the data we have seen so far, edoxaban has been shown to be an effective anticoagulant with a predictable pharmacokinetic and pharmacodynamic profile, which allows for a convenient, once-daily dosing. The data are encouraging and support the potential for edoxaban in anticoagulation management while being effective against thromboembolic events."

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

About Edoxaban is a once-daily oral anticoagulant that directly inhibits Factor Xa, an important factor in the coagulation process. Edoxaban is currently only approved in

Japan, licensed for the prevention of venous thromboembolism (VTE) in patients undergoing total knee arthroplasty, total hip arthroplasty and hip fracture surgery. 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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