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Daiichi-Sankyo

Press Release

Daiichi Sankyo Launches New Formulation of LIXIANA® 60 mg Tablets (edoxaban) in Japan

Tokyo, Japan, December 8, 2014 – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has launched a new formulation of LIXIANA® 60 mg Tablets (JAN: Edoxaban Tosilate Hydrate, INN: edoxaban, approval to market: September 26, 2014; NHI drug price listing: November 25, 2014) in Japan for the recently approved indications: the prevention of ischemic stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAF) and the treatment and recurrence prevention of venous thromboembolism (VTE) [deep vein thrombosis (DVT) and pulmonary thromboembolism (PE)].

LIXIANA was approved in Japan in April 2011, for the prevention of VTE after major orthopedic surgery and was launched in July 2011.[1] LIXIANA was also approved in Japan in September 2014 for the prevention of ischemic stroke and systemic embolism in patients with NVAF and for the treatment and recurrence prevention of VTE.[2] Daiichi Sankyo has also filed for approval of once-daily edoxaban in both the U.S. and EU for the reduction in risk of stroke in NVAF and for symptomatic VTE in patients with DVT and/or PE.[3,4]

About Atrial Fibrillation

Atrial fibrillation (AF) is a condition in which the heartbeat is rapid and irregular, and can potentially lead to a stroke.[5] AF is a common condition, affecting approximately 2.3-3.4% of people in developed nations.[6] AF affects approximately 6 million people in the EU,[7] approximately 6.1 million people in the U.S.,[8] approximately 1.5 million people in Brazil,[9] and more than 800,000 people in Japan.[10] Stroke due to all causes is the second most common cause of death worldwide, responsible for approximately 6.2 million deaths each year.[11] Compared to those without AF, people with the arrhythmia have a 3-5 times higher risk of stroke.[6] Strokes due to AF are nearly twice as likely to be fatal than strokes in patients without AF at 30 days and have poorer prognosis than non-AF related strokes, with a 50% increased risk of remaining disabled at three months.[12,13]

About Venous Thromboembolism

VTE is an umbrella term for two conditions, DVT and PE. DVT is a blood clot found anywhere in the deep veins of the legs, while PE occurs when part of a clot detaches and lodges in the pulmonary arter-

ies, causing a potentially fatal condition.[14] VTE is a major cause of morbidity and mortality worldwide with an annual incidence estimated at one per 1,000 (with some age and regional variation).[15] In Japan, there is an estimated annual incidence of 0.19% for DVT and 0.05% for PE.[16] In the EU, it is estimated that 430,000 PE events, 680,000 DVT events and 540,000 deaths occur each year.[17] In the U.S., it is estimated that more than 950,000 VTE events and approximately 300,000 VTE related deaths occur each year.[18,19]

About Edoxaban

Edoxaban is an investigational, oral, once-daily anticoagulant that specifically inhibits factor Xa, which is an important factor in the coagulation system that leads to blood clotting.[20] The global edoxaban clinical trial program includes two phase 3 clinical studies, Hokusai-VTE and ENGAGE AF-TIMI 48 (**E**ffective a**N**ticoa**G**ulation with factor x**A** next **GE**neration in **A**trial **F**ibrillation), which included nearly 30,000 patients combined. The results from these trials form the basis of regulatory filings for edoxaban for symptomatic VTE in patients with DVT and/or PE, and for the prevention of stroke in NVAF, respectively.[21,22] Edoxaban is currently under regulatory review in the U.S. and the EU for these indications.

About Daiichi Sankyo

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, dyslipidemia and bacterial infections used by patients around the world, the Group has also launched treatments for thrombotic disorders and is building new product franchises. Furthermore, Daiichi Sankyo research and development is focused on bringing forth novel therapies in oncology and cardiovascular-metabolic diseases, including biologics. The Daiichi Sankyo Group has created a “Hybrid Business Model,” to 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

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. 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. 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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