

## Press Release

### Daiichi Sankyo Submits Supplemental New Drug Application in Japan for LIXIANA<sup>®</sup> (Edoxaban Tosilate Hydrate) for New Indications

- *Submission based on the two largest comparative phase 3 clinical trials of a novel oral anticoagulant in patients with non-valvular atrial fibrillation or symptomatic venous thromboembolism*
- *Regulatory filings for once-daily edoxaban planned by Q1 2014 in the U.S. and Europe*

**Tokyo, Japan (December 19, 2013)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has submitted a supplemental New Drug Application (NDA) for its oral, once-daily direct factor Xa-inhibitor LIXIANA<sup>®</sup> (Edoxaban Tosilate Hydrate) for review by the Japanese Ministry of Health, Labour and Welfare. Daiichi Sankyo is seeking approval in Japan for edoxaban in new indications for non-valvular atrial fibrillation (AF) and symptomatic venous thromboembolism (VTE).

The supplemental NDA submission is based on data from an extensive global clinical trial program that compared treatment with once-daily edoxaban to warfarin, a current standard of care for patients with AF or VTE. The two clinical trials that formed the basis of the submission, ENGAGE AF-TIMI 48 and Hokusai-VTE, are the largest comparative trials of a novel oral anticoagulant in these patient populations, involving 21,105 and 8,292 patients, respectively.<sup>1,2</sup>

“The submission of our supplemental NDA in Japan for edoxaban represents our long standing commitment to addressing the needs of patients living with cardiovascular diseases, including those living with atrial fibrillation or venous thromboembolism,” said Glenn Gormley, MD, PhD, Senior Executive Officer and Global Head of Research and Development, Daiichi Sankyo Co., Ltd. and President and CEO of Daiichi Sankyo, Inc. in the United States. “We look forward to working with the Japanese Ministry of Health, Labour and Welfare throughout its review of these new indications for edoxaban. Additionally, we plan to submit applications for edoxaban in the U.S. and Europe by the first quarter of 2014.”

## **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.<sup>3</sup> The global edoxaban clinical trial program includes two phase 3 clinical studies, Hokusai-VTE and ENGAGE AF-TIMI 48 (Effective aNticoaGulation with Factor XA Next GEneration in Atrial Fibrillation). The results from these trials form the basis of the supplemental NDAs for edoxaban for symptomatic VTE in patients with deep vein thrombosis (DVT) and/or pulmonary embolism (PE), and for non-valvular AF, respectively.

Edoxaban is currently approved only in Japan, since April 2011, for the prevention of VTE after major orthopedic surgery, and was launched in July 2011 under the brand name LIXIANA<sup>®</sup>. Elsewhere, including Europe and the U.S., edoxaban is currently in phase 3 clinical development and has not been approved in any indication.<sup>4</sup>

## **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, 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](http://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.

## References

1. Giugliano, R et al. Edoxaban versus Warfarin in Patients with Atrial Fibrillation. *N Engl J Med* 2013;369:2093-2104.
2. Büller, H et al. Edoxaban versus Warfarin for the treatment of Symptomatic Venous Thromboembolism. *N Engl J Med* 2013;369:1406-1415.
3. Ogata, K et al. Clinical Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of the Novel Factor Xa Inhibitor Edoxaban in Healthy Volunteers. *J Clin Pharmacol* 2010;50:743-753.
4. Daiichi Sankyo press release - Daiichi Sankyo Launches LIXIANA® (edoxaban), a Direct Oral Factor Xa Inhibitor, in Japan for the Prevention of Venous Thromboembolism after Major Orthopaedic Surgery. 19 July 2011. Available at: [http://www.daiichisankyo.com/media\\_investors/media\\_relations/press\\_releases/detail/005784.html](http://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/005784.html). [Last accessed: December 2013].