



**Daiichi-Sankyo**

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**DAIICHI SANKYO INITIATES PHASE III TRIAL OF ITS INVESTIGATIONAL  
FACTOR Xa INHIBITOR, DU-176b, IN PATIENTS WITH ATRIAL FIBRILLATION**

*ENGAGE-AF TIMI 48 Trial to Study 16,500 Patients in More Than 1,400 Centers  
Globally*

**Tokyo, Japan and Edison, N.J. – December 7, 2008** – Daiichi Sankyo Company, Limited (TSE: 4568), announced today that it has initiated its pivotal Phase III trial for DU-176b, an investigational oral Factor Xa inhibitor, in patients with atrial fibrillation. DU-176b is being developed solely by Daiichi Sankyo.

The Phase III global study, Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation (ENGAGE-AF TIMI 48), will compare DU-176b with warfarin in preventing stroke and systemic embolic events (SEE) in patients with atrial fibrillation. The primary safety assessment will be the incidence of bleeding.

Results from a recently presented Phase II safety study showed that the incidence of major and clinically relevant non-major bleeding events reported in the once-daily DU-176b treatment groups (30 mg or 60 mg) was similar to that in the warfarin-treated patient group. The incidence of major and clinically relevant non-major bleeding events was significantly higher in the twice-daily DU-176b treatment groups (30 mg or 60 mg), compared to the warfarin group. The Phase III study will therefore randomize approximately 16,500 patients to one of three treatment groups: 30 mg DU-176b once

daily, 60 mg DU-176b once daily, or warfarin. Those randomized to warfarin will be dosed once daily with dose adjustments to maintain International Normalized Ratio (INR) between 2.0 and 3.0.

This is an event-driven, Phase III, multinational, randomized, double-blind study with sites in North and South America, Africa, Asia, Europe, Australia and New Zealand. The expected median treatment duration of the study is 24 months; Daiichi Sankyo expects the study to conclude in the first half of 2012.

“There is a need for a safe and effective option for the prevention of clotting or stroke in patients with atrial fibrillation other than the current standard of care, warfarin, which requires extensive monitoring and poses potentially serious drug and food interactions,” said John Alexander, M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited. “The start of our Phase III trial marks an important milestone in the clinical development of DU-176b and we hope this compound will prove to be another successful treatment in our cardiovascular portfolio.”

### **About Atrial Fibrillation**

Atrial fibrillation (AF) is an irregular heartbeat caused when the upper chambers of the heart (the atria) beat inconsistently and rapidly. When this happens, blood can become stagnant near the walls of the atria and form blood clots. These blood clots can break off and travel through the blood stream to the brain where they can block blood vessels possibly causing a stroke. These clots can also cause damage to other organs in the body by blocking peripheral arteries.

About 90,000 strokes in the U.S. are caused by atrial fibrillation.<sup>1</sup> Patients with atrial fibrillation have five times higher risk of having a stroke.<sup>2</sup> These patients also tend to have more serious first strokes than patients without atrial fibrillation, resulting in higher mortality rates and longer hospital stays.<sup>1</sup>

### **About DU-176b**

DU-176b is an oral anticoagulant that directly inhibits Factor Xa, a clotting factor in the blood. Daiichi Sankyo is developing DU-176b as a potential new treatment for the prevention of both arterial and venous thromboembolism. Notably, Daiichi Sankyo has

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<sup>1</sup> Jorgensen, H.S., Nakayama, H, Reith, J. et. al. Acute stroke with atrial fibrillation. *Stroke* 1996;27: 1765-1769.

<sup>2</sup> Hylek AM, et al. *N Engl J Med.* 2003; 349:1019-1026.

more than 25 years experience conducting research in the area of Factor Xa inhibition and was the first company to test these compounds in humans.

### **About Daiichi Sankyo**

A global pharma innovator, Daiichi Sankyo Co., Ltd., was established in 2005 through the merger of two leading Japanese pharmaceutical companies. This integration created a more robust organization that allows for continuous development of novel drugs that enrich the quality of life for patients around the world. A central focus of Daiichi Sankyo's research and development are thrombotic disorders, malignant neoplasm, diabetes mellitus, and autoimmune disorders. Equally important to the company are hypertension, hyperlipidemia or atherosclerosis and bacterial infections. For more information, visit [www.daiichisankyo.com](http://www.daiichisankyo.com).

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Co., Ltd. For more information on Daiichi Sankyo, Inc., please visit [www.dsus.com](http://www.dsus.com).

### **Forward-Looking Statements**

*This news release may contain forward-looking statements based on current assumptions and forecasts made by Daiichi Sankyo group. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports, which are available on the website at [www.daiichisankyo-us.com](http://www.daiichisankyo-us.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.*

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