



Daiichi-Sankyo

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**NEW PHASE II DATA SHOW SAFETY OF ONCE-DAILY ORAL
FACTOR Xa INHIBITOR, DU-176b, COMPARABLE TO WARFARIN IN PATIENTS
WITH NON-VALVULAR ATRIAL FIBRILLATION**

SAN FRANCISCO, December 7, 2008 – Patients with non-valvular atrial fibrillation receiving either 30 mg or 60 mg once-daily dose of DU-176b, an investigational oral Factor Xa inhibitor, experienced comparable safety and tolerability compared to those taking warfarin, according to new Phase II data presented today at the 50th Annual Meeting of the American Society of Hematology in San Francisco. These findings are the first results from a Phase II clinical study evaluating an oral Factor Xa inhibitor in atrial fibrillation patients. DU-176b is being developed solely by Daiichi Sankyo Company, Limited (TSE: 4568).

The objective of the multinational study was to assess the safety of four dose regimens of DU-176b in patients with non-valvular atrial fibrillation (AF), as compared to warfarin. While 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 twice per day), compared with warfarin, the incidence reported in the once-daily DU-176b treatment groups (30 mg or 60 mg once per day) was similar to that in the warfarin-treated patient group. Bleeding events were evaluated using guidelines established by

the International Society on Thrombosis and Haemostasis¹, the most sensitive scale of those currently used in clinical studies in cardiovascular disease.

“These results are noteworthy and encouraging because we observed significantly fewer adverse bleeding events in patients receiving one dose of DU-176b per day, versus two doses per day, suggesting with this compound, the most convenient dosing regimens also appear to be safer,” said Jeffrey I. Weitz, MD, FACP, FRCP, professor of medicine and biochemistry, McMaster University and director, Henderson Research Centre, Hamilton, Ontario. “These data provide insight into the optimal dosing regimens for Phase III studies of DU-176b.”

“Having clear results from a robust Phase II study among atrial fibrillation patients gives us confidence in evaluating the doses selected for our Phase III clinical trial,” said Francis Plat, M.D., vice president, clinical development at Daiichi Sankyo Pharma Development. “We are hopeful that DU-176b may one day provide the community with a safe and convenient treatment for the prevention of stroke in patients with non-valvular atrial fibrillation.”

About the DU-176b Phase II Safety Study

A total of 1,146 patients with atrial fibrillation with a CHADS₂ index ≥ 2 were enrolled in the study. Patients were randomly assigned to receive either one of the four fixed dose regimens of DU-176b (30mg/N=235 or 60mg/N=234 administered once daily; 30mg/N=244 or 60mg/N=180 administered twice daily), or warfarin (N=250) dose-adjusted locally to a target International Normalized Ratio (INR) of 2.0-3.0 for 12 weeks. The INR was determined weekly for four weeks and every two weeks thereafter. Investigators, sponsors and study subjects were blinded to the DU-176b dose; however, those taking warfarin were aware they were randomized to the warfarin arm.

The primary endpoints of the study were the incidence of bleeding events (major and clinically relevant non-major) and elevated liver enzymes and/or bilirubin. Secondary endpoints included major adverse cardiovascular events, stroke, systemic embolism, acute myocardial infarction, hospitalizations due to cardiovascular conditions or cardiovascular death.

¹Schulman S., et al. Definition of major bleeding in clinical investigations of antihemostatic medicinal products in non-surgical patients. *Journal of Thrombosis and Haemostasis* 2005;3: 692–694.

The incidence of major and clinically relevant non-major bleeding events was significantly higher with the 30 mg and 60 mg twice-daily DU-176b regimens (7.8 percent, $p = 0.029$ and 10.6 percent, $p = 0.002$ respectively) than it was in patients given warfarin (3.2 percent). In contrast, the incidence of major and clinically relevant non-major bleeding events with the 30 mg and 60 mg once-daily DU-176b regimens was comparable to that with warfarin (3.0 percent, 3.8 percent and 3.2 percent, respectively). There were no significant differences in the numbers of patients with elevated liver enzymes or bilirubin across all treatment groups. Although the study was not powered to detect efficacy, there were no significant differences in the rates of secondary efficacy endpoints across treatment groups.

About Atrial Fibrillation

Atrial fibrillation 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 plug blood vessels possibly causing a stroke. These clots can also cause damage to other organs in the body by blocking peripheral arteries.

Approximately 90,000 strokes in the U.S. result from atrial fibrillation.² Patients with atrial fibrillation have five times higher risk of having a stroke.³ These patients also tend to have more serious first strokes than those without atrial fibrillation, resulting in higher mortality rates and longer hospital stays.¹

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 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

² Jorgensen, H.S., Nakayama, H, Reith, J. et. al. Acute stroke with atrial fibrillation. *Stroke* 1996;27: 1765-1769.

³ Hylek AM, et al. *N Engl J Med.* 2003; 349:1019-1026.

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.

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.

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. 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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