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ANALYSIS OF EDOXABAN PHASE II DATA PROVIDES INSIGHT INTO REDUCED BLEEDING EVENTS SEEN IN ONCE-DAILY DOSING

-- Pharmacokinetic Analysis of Atrial Fibrillation Study May Explain Bleeding Rate Difference between Once-Daily and Twice-Daily Dosing Regimens with Same Total Exposure of Factor Xa Inhibitor --

BOSTON and Edison, N.J. – July 15, 2009 – A sub-analysis of a Phase IIb multinational study[1] with edoxaban[2] – an investigational oral Factor Xa inhibitor – provides insights into why patients with non-valvular atrial fibrillation (AF) receiving edoxaban once daily (QD) experienced fewer bleeding events than patients given edoxaban twice a day (BID). The analysis finds that bleeding associated with edoxaban is most closely correlated with minimum concentration levels of the drug in the blood, and that these trough levels may best predict bleeding events, rather than total exposure or maximum concentration levels.

These findings were presented today at the XXII International Society on Thrombosis and Haemostasis Congress in Boston. Edoxaban is being developed solely by Daiichi Sankyo Company, Limited (TSE: 4568) as a potential treatment for the prevention of both arterial and venous thromboembolism; a Phase III trial is underway among patients with AF.

[1] Randomized, Parallel Group, Multicenter, Multinational Study Evaluating Safety of DU-176b Compared with Warfarin in Subjects with Non-Valvular Atrial Fibrillation," presented at American Society of Hematology annual meeting in December 2008.
[2] Edoxaban tosylate is also known as DU-176b.

This pharmacokinetic (PK) analysis of the Phase IIb study examined the relationship between bleeding events reported in patients taking 30 or 60 mg edoxaban given either QD or BID and the concentration of edoxaban in their blood. The analysis examined overall bleeding rates when drug concentration levels reached the highest points (known as Cmax), lowest points (known as Cmin) as well as overall edoxaban exposure (measured by area under the curve or AUC). Delivering a compound twice per day generally allows for more consistent concentration levels in the blood. With twice-daily dosing, the Cmin levels (troughs) do not dip as low, and the Cmax levels (peaks) do not reach as high as when the compound is delivered once per day.

"When we assessed the pharmacokinetics in patients taking edoxaban once a day, lower minimum concentrations and fewer bleeding events were observed, compared to the same total daily dosage given twice a day," said Robert P. Giugliano, M.D., S.M., Associate Physician, Cardiovascular Division, Brigham and Women's Hospital. "These results countered our expectations that patients with higher maximum concentrations of edoxaban, in this case, those that received their total dose once daily, would have the most bleeding events. It may be that reaching lower Cmin levels with edoxaban once-a-day permits some degree of normal hemostasis to be temporarily reestablished, and that may be the reason why bleeding rates are lower with once-daily dosing."

“This Phase II study was a decisive study for Daiichi Sankyo in that it directed us to the optimal dosing regimen to study in our Phase III clinical trial ENGAGE AF-TIMI 48 – the more convenient 60 and 30 mg once-daily doses,” said Francis Plat, M.D., vice president, clinical development at Daiichi Sankyo Pharma Development.

About the Phase IIb Safety Study

A total of 1,146 patients with AF with a $CHADS_2$ index ≥ 2 were enrolled in the initial Phase II study for three months. Patients were randomly assigned to receive either one of the four fixed dose regimens of edoxaban (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 edoxaban dose; however, those taking warfarin were aware they were randomized to the warfarin arm.

Bleeding events were evaluated using guidelines established by the International Society on Thrombosis and Haemostasis[3], the most sensitive scale of those currently used in clinical studies in cardiovascular disease. In the treatment groups receiving a once-daily dose of edoxaban, the lowest bleeding rates were observed in 17 patients (7.3 percent) in the 60 mg QD (N=234) and 13 patients (5.5 percent) in the 30 mg QD (N=235). In the treatment groups receiving a twice-daily dose of edoxaban, the highest bleeding rates were observed in 33 patients (18.3 percent) in the 60 mg BID (N=180) and 31 patients (12.7 percent) in the 30 mg BID (N= 244). This sub-analysis examined only the population receiving edoxaban from the initial study. PK samples were taken before dosing and one to three hours post-dosing on day 28. The relationship between PK and all bleeding events was examined using logistical regression.

About Edoxaban

Edoxaban, the molecule originally referred to as DU-176b, is an oral anticoagulant that directly inhibits Factor Xa, a clotting factor in the blood. Daiichi Sankyo is developing edoxaban 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.

Daiichi Sankyo is actively enrolling 16,500 patients in its pivotal Phase III trial for edoxaban in patients with atrial fibrillation. The Phase III study, Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation (ENGAGE-AF), is comparing edoxaban with warfarin (INR2-3) for the prevention of stroke and systemic embolic events (SEE) in patients with atrial fibrillation. Edoxaban is also being studied for treatment of VTE, and for the prevention of DVT after major orthopaedic surgery.

About Daiichi Sankyo

A global pharmaceutical 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 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.

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[3] Schulman 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.

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.dsi.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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