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New Study Shows Prasugrel Achieves Faster Onset and Higher Levels of Platelet Inhibition than Clopidogrel at Approved or Higher Doses

INDIANAPOLIS, Ind., and TOKYO, Japan – In a Phase I study, a 60 mg loading dose of the investigational antiplatelet compound prasugrel showed faster onset of activity and achieved greater inhibition of platelet aggregation than either the approved 300 mg loading dose of clopidogrel (Plavix®) or a higher 600 mg clopidogrel dose, researchers with Daiichi Sankyo and Eli Lilly and Company presented today.

Thirty minutes after oral administration, the level of platelet inhibition with a prasugrel 60 mg dose was significantly higher than observed with either loading dose of clopidogrel. At one hour, the antiplatelet inhibition achieved with a prasugrel loading dose was greater than that seen at up to six hours following administration of the approved and high loading doses of clopidogrel.

"This data shows for the first time that as early as 30 minutes after dosing, a 60 mg prasugrel loading dose achieves greater platelet inhibition than both the approved loading dose and high-dose clopidogrel," said Kenneth Winters, M.D., Lilly research cardiologist.

In an earlier Phase I study with healthy volunteers, a 60 mg loading dose of prasugrel showed a lower rate of poor responders by platelet function testing compared with the approved 300 mg loading dose of clopidogrel. Poor responders are defined as those who fail to reach a specified level of platelet inhibition after receiving the drug. Findings showed poor antiplatelet response in 17 percent to 43 percent of those given the approved clopidogrel loading dose (depending on the definition of poor responder used); while no poor responders were observed with prasugrel.

Winters presented the new clinical data today in an oral presentation at the Cardiovascular Research Foundation's 18th annual Transcatheter Cardiovascular Therapeutics meeting in Washington, D.C. Data from the other Phase I study appeared in a poster presentation at the meeting.

Daiichi Sankyo and Lilly are currently studying prasugrel in the Phase III head-to-head clinical trial TRITON-TIMI 38. The TRITON-TIMI 38 study will evaluate the safety and efficacy of prasugrel compared with clopidogrel in reducing ischemic events such as heart attacks, stroke and death in approximately 14,000 patients with acute coronary syndrome undergoing percutaneous coronary intervention, including coronary stenting. The study is expected to be completed in 2007, and, if successful, regulatory submissions will follow in the same year.

About the studies

In the Phase I study, "Inhibition of Platelet Aggregation Following Loading and Maintenance Dose Administration of 60/10 mg Prasugrel, 300/75 mg and 600/75 mg Clopidogrel In Healthy Subjects," loading and maintenance doses of prasugrel (60 mg and 10 mg, respectively) were compared with 600 mg and 300 mg clopidogrel loading

doses (both given with the approved clopidogrel 75 mg maintenance dose) in a three-period crossover study in 41 aspirin-free healthy subjects. A seven-day maintenance dose schedule followed the loading dose, followed by a 14-day washout period before the next treatment period. Researchers used turbidometric aggregometry, considered the gold standard of testing platelet function, to measure the inhibition of platelet aggregation (IPA) to 20µM ADP.

The study used a crossover design in which the same individuals received each of the three medication regimens, on three separate occasions, allowing researchers to compare in each individual the antiplatelet response of prasugrel to either 300 mg or 600 mg clopidogrel.

Thirty minutes following initial oral administration of a 60 mg prasugrel loading dose, inhibition of platelet aggregation (IPA, to 20 µM ADP) was significantly higher at 52.1 percent, compared with 4.3 percent for clopidogrel 600 mg ($p<0.001$) and 1.3 percent for clopidogrel 300 mg ($p<0.001$). Four hours after initial administration, prasugrel 60 mg maintained significantly greater IPA versus both high-dose and approved-dose clopidogrel: 89.7 percent for prasugrel compared with 64.1 percent for clopidogrel 600 mg ($p<0.001$) and 42.4 percent for clopidogrel 300 mg ($p<0.001$).

The study also showed that a 10 mg maintenance dose of prasugrel resulted in higher and less variable platelet inhibition than the approved 75 mg maintenance dose of clopidogrel.

In findings from "A 60 mg Loading Dose of Prasugrel Produces a Lower Rate of Poor Responders Compared to a 300 mg Loading Dose of Clopidogrel," a 60 mg loading dose of prasugrel resulted in a significantly lower rate of poor responders as assessed by aggregometry compared with a 300 mg loading dose of clopidogrel. Platelet aggregometry data from five studies in healthy subjects were integrated and analyzed to compare antiplatelet activity response rates between prasugrel (n=109) and clopidogrel (n=131). Maximal platelet aggregation in response to ADP (20 µM) was determined at baseline, and two hours, four to five hours (4/5), and 24 hours following dosing.

There were significantly more poor responders, as defined by platelet function testing using aggregometry, with clopidogrel 300 mg than for prasugrel 60 mg ($p<0.005$, McNemar's test vs. prasugrel). With clopidogrel the number of poor responders ranged from 17 percent (4/5 hours; criteria=IPA<10 percent) to 43 percent (2 hours; criteria=IPA<20 percent). No poor responders to prasugrel 60 mg were observed for 20 µM ADP.

"There is room to continue to improve therapy for patients with acute coronary syndrome," said Francis Plat, M.D., Daiichi Sankyo vice president of Cardiovascular Development. "Our Phase III clinical program will evaluate whether the greater, faster and more reliable platelet inhibition seen in early studies comparing prasugrel to clopidogrel translates into improved clinical outcomes."

Doctors use antiplatelet agents for both acute and maintenance therapy to inhibit platelet activation and aggregation that occur in diseased arteries and as adjunct therapy to invasive procedures such as percutaneous coronary intervention, a procedure to open blockages in heart arteries through placement of coronary stents. Recent studies suggest that a relationship may exist between a poor platelet response to antiplatelet agents in individual patients and poor clinical outcomes, which can manifest as major adverse cardiovascular events, including heart attacks[i,ii,iii]

Cardiovascular disease is the leading cause of death in the U.S. and worldwide, killing 17 million people each year.[iv] Acute heart attacks and unstable angina, called acute coronary syndrome, affect more than 942,000 Americans each year. Despite current medical interventions, 300,000 people experience recurrent heart attacks and 500,000 people die from heart attacks annually in the U.S.[v]

About prasugrel

Eli Lilly and Company (NYSE: LLY) and Sankyo Company Ltd., a subsidiary of Daiichi Sankyo Company, Limited (TSE: 4568) are developing prasugrel, an investigational oral

antiplatelet agent, as a potential treatment for patients who have suffered a heart attack or unstable angina (heart-related chest pain). Prasugrel is designed to inhibit platelet activation and aggregation by blocking the P2Y12 adenosine diphosphate (ADP) receptor on the platelet surface. Antiplatelet agents prevent platelets from clumping or sticking together, which can cause formation of blood clots and lead to heart attack or stroke.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first in class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers – through medicines and information – for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.
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About Daiichi Sankyo Company, Limited

Daiichi Sankyo Company, Limited was established on Sept. 28, 2005, as the joint holding company of two major Japanese pharmaceutical companies – Sankyo Co., Ltd., and Daiichi Pharmaceutical Co., Ltd. Daiichi Sankyo is a global pharmaceutical innovator, continuously generating innovative drugs and services and maximizing its corporate value. Both companies have used their cumulative knowledge and expertise in the field of cardiovascular disease as a foundation for developing an abundant product lineup and R&D pipeline. For further details, please refer to the company Web site at www.daiichisankyo.co.jp/english.

This press release contains certain forward-looking statements about the potential of the investigational compound prasugrel (CS-747, LY640315) and reflects Lilly's current beliefs. However, as with any pharmaceutical compound under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that the compound will receive regulatory approvals, or that the regulatory approval will be for the indication(s) anticipated by the company. There is also no guarantee that the compound will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filing with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.
Plavix® is a registered trademark of Sanofi-Synthelabo Inc.

[i] Barragan, P., Bouvier, J. L., Roquebert, P. O., Macaluso, G., Commeau, P., Comet, B., Lafont, A., Camoin, L., Walter, U., and Eigenthaler, M. Resistance to thienopyridines: clinical detection of coronary stent thrombosis by monitoring of vasodilator-stimulated phosphoprotein phosphorylation. *Catheter Cardiovasc Interv* 2003; 59: 295-302

[ii] Muller, I., Besta, F., Schulz, C., Massberg, S., Schonig, A., and Gawaz, M. Prevalence of clopidogrel non-responders among patients with stable angina pectoris scheduled for elective coronary stent placement. *Thromb Haemost* 2003; 89: 783-787

[iii] Matetzky, S., Shenkman, B., Guetta, V., Shechter, M., Bienart, R., Goldenberg, I., Novikov, I., Pres, H., Savion, N., Varon, D., and Hod, H. Clopidogrel resistance is associated with increased risk of recurrent atherothrombotic events in patients with acute myocardial infarction. *Circulation* 2004; 109: 3171-3175.

[iv] World Health Organization. The Atlas of Heart Disease and Stroke - Types of Cardiovascular Disease 2005.

[v] American Heart Association. Heart Disease and Stroke Statistics 2005.

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