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Results of Early Data Show More Consistent Platelet Inhibition with Prasugrel Compared to Clopidogrel Across Three Distinct Trials

INDIANAPOLIS, and TOKYO, March 9, 2005 /PRNewswire-FirstCall via COMTEX/ -- In three early- phase trials,(1,2,3) an investigational platelet inhibitor, prasugrel (CS-747, LY640315), demonstrated significantly higher and more consistent inhibition of platelet aggregation (IPA) compared to both placebo and the current standard of care, clopidogrel (Plavix(R)).

While each study was distinct in design and outcome, all three showed that prasugrel prevented platelets from aggregating better than clopidogrel. The data showed that response to prasugrel was consistent in terms of less variability in response rates and IPA achieved.

Data from these studies were presented this week at the American College of Cardiology annual scientific sessions in Orlando, Fla.

"The results from these early studies are very encouraging," said John T. Brandt, MD, a senior-level physician at Eli Lilly and Company (NYSE: LLY). "A more consistent, faster and greater level of platelet inhibition could have important implications for patient care." Eli Lilly and Company and Sankyo Company, Ltd. (TSE: 4501) are developing prasugrel as a potential treatment for patients who have suffered a heart attack or unstable angina (heart- related chest pain).

A Phase III clinical study with prasugrel is ongoing, the TRITON-TIMI 38 study. This study compares the effects of prasugrel with clopidogrel in up to 13,000 patients with acute coronary syndrome who are to undergo percutaneous coronary intervention (PCI). PCI is a procedure to open blockages in heart arteries, including the use of coronary stents. The primary focus of the study is to compare the agents' ability to prevent heart attack, stroke and death in patients who undergo PCI. The secondary focus is to look at the impact on bleeding, hospitalization for recurrent heart-related chest pain (ischemia) or the need for additional procedures to restore blood flow (urgent target vessel revascularization). Investigators interested in enrolling patients in TRITON-TIMI 38 should call (800) 385-4444.

"We're looking forward to building on the data presented here at ACC," said Eugene Braunwald, MD, Distinguished Hersey Professor of Medicine, Harvard Medical School, Boston, MA, and lead investigator of the TRITON-TIMI 38 study. "TRITON is testing whether prasugrel's differential effects on platelets will translate into clinical benefits for patients."

Added Fortunato Senatore, MD, PhD, a senior-level physician at Sankyo: "We are hopeful that prasugrel will be a promising addition to the developing class of ADP receptor antagonists. This class of drug has revolutionized the practice of cardiology, particularly with respect to percutaneous coronary intervention."

Heart disease and stroke kill about 17 million people a year, which is almost one-third of all deaths globally. By 2020, heart disease and stroke will become the leading cause of both death and disability worldwide, with the number of fatalities projected to increase to over 20 million a year and by 2030 to over 24 million a year.(4)

About the Studies

In one Phase I study ("Superior Responder Rate for Inhibition of Platelet Aggregation With a 60 mg Loading Dose of Prasugrel (CS-747, LY640315) Compared With a 300 mg Loading Dose of Clopidogrel" - abstract 868-5), 68 healthy subjects were randomized to receive either a 60 mg loading dose of prasugrel or the approved 300 mg loading dose of clopidogrel in a 2-way cross-over design. In this study, all prasugrel-treated patients (100%) achieved a greater than 25 percent inhibition of platelet aggregation compared to 42.4% of clopidogrel-treated patients who achieved this level of platelet inhibition (p less than or equal to .001).

In a separate, double-blind, placebo-controlled multiple oral dose Phase I study ("A Comparison of Prasugrel (CS-747, LY640315) With Clopidogrel on Platelet Function in Healthy Male Volunteers" - abstract 868-8), 30 healthy male volunteers were randomized to receive potential maintenance doses of prasugrel 5 mg, 10 mg or 20 mg, the approved clopidogrel maintenance dose of 75 mg, or placebo. Study medications were taken once daily for 10 days and bleeding times and platelet aggregation were measured in laboratory tests. After 10 days, the maximum level of platelet inhibition was greater for all prasugrel doses than for 75 mg clopidogrel (p less than or equal to 0.011).

The third Phase I study ("Inhibition of Platelet Aggregation with Prasugrel (CS-747, LY640315), a Novel Thienopyridine P2Y (12) Receptor Antagonist, Compared with Clopidogrel in Aspirin-Treated Patients with Atherosclerotic Vascular Disease" - abstract 1126-136) was conducted in 101 patients with stable atherosclerotic vascular disease. Aspirin-treated patients were randomly assigned to one of five oral dosing regimens (four prasugrel dosing regimens and one clopidogrel dosing regimen). Patients receiving 40 and 60 mg loading doses of prasugrel achieved significantly higher levels of platelet inhibition compared to the approved 300 mg loading dose of clopidogrel ($p < 0.05$). After 28 days, patients receiving 10 and 15 mg maintenance doses of prasugrel achieved higher levels of platelet inhibition than those taking the 75 mg dose of clopidogrel (p less than or equal to 0.0002). There was a trend toward more bruising and minor bleeding with the 15 mg maintenance dose of prasugrel.

About Prasugrel

Prasugrel is an investigational anti-platelet agent designed to prevent platelet activation and aggregation by blocking adenosine diphosphate receptors on the platelet surface. This novel oral compound was discovered by Sankyo and Ube Industries, Ltd. (TSE: 4208). It is being investigated as a potential treatment for higher risk patients with acute coronary syndrome who undergo percutaneous coronary intervention (PCI).

About Lilly

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. Building on the strong foundation of ReoPro, Lilly is in the process of building a robust cardiovascular pipeline. Lilly has multiple cardiovascular drugs in that pipeline -- in every stage from pre-clinical and Phase I to the Phase III trials for prasugrel. Additional information is available at www.lilly.com. P-LLY

About Sankyo

Sankyo Co., Ltd. of Tokyo, one of Japan's largest pharmaceutical companies, has a long history of discovering new classes of drugs, including the statin class of lipid-lowering drugs. Beginning with the discovery of the first statin, mevastatin, and the co-discovery of lovastatin, the first statin to be marketed, Sankyo has been a pioneer in the cardiovascular disease arena. Additionally, Sankyo discovered, developed, manufactures and markets pravastatin sodium and olmesartan medoxomil, an angiotensin II receptor blocker (ARB). For further information about Sankyo and its products, log on to <http://www.sankyo.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 product under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that the product 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 product 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(R) is a registered trademark of Sanofi-Synthelabo Inc.

(1) A Comparison of Prasugrel (CS-747, LY640315) With Clopidogrel on Platelet Function in Healthy Male Volunteers; Fumitoshi Asai, Joseph A. Jakubowski et al. Presented at American College of Cardiology March 9, 2005

(2) Inhibition of Platelet Aggregation With Prasugrel (CS-747, LY640315), A Novel Thienopyridine P2Y₁₂ Receptor Antagonist, Compared With Clopidogrel in Aspirin-Treated Patients With Atherosclerotic Vascular Disease; Lars Wallentin, John T. Brandt et al. Presented at American College of Cardiology March 8, 2005

(3) Superior Responder Rate for Inhibition of Platelet Aggregation With a 60 mg Loading Dose of Prasugrel (CS-747, LY640315) Compared With a 300 mg Loading Dose of Clopidogrel; John T. Brandt, Christopher D. Payne et al, Presented at American College of Cardiology March 9, 2005

(4) World Health Organization Web site, <http://www.who.int/en/>, accessed March 2005

(Logo: <http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO>

<http://www.newscom.com/cgi-bin/prnh/20040827/SANKYO>)

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