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New Crossover Study Shows Prasugrel Significantly Reduced Platelet Aggregation in Patients with Acute Coronary Syndromes Compared with Clopidogrel at High Doses

ACAPULCO study showed that 10 mg Prasugrel Maintenance Dose Achieved Higher Platelet Inhibition than 150 mg Clopidogrel Maintenance Dose

MUNICH, Germany (September 3, 2008) – Among patients with acute coronary syndromes (ACS) who are administered a 900 mg loading dose of clopidogrel, does a maintenance dose of 150 mg of clopidogrel or 10 mg of prasugrel better inhibit platelets from aggregating together and forming blood clots? The answer: a 10 mg maintenance

dose of prasugrel, according to the results of a randomized, double-blind, crossover study.

Results of this study, known as the ACAPULCO¹ trial, showed that the 10 mg prasugrel maintenance dose significantly reduced the level of maximum platelet aggregation by 12.9 percent compared to the 150 mg clopidogrel maintenance dose ($P < 0.001$). These findings were presented today at the Congress of the European Society of Cardiology (ESC) in Munich, Germany.

"This study provides the first evidence of the greater antiplatelet effect of a 10 mg prasugrel maintenance dose versus a 150 mg clopidogrel maintenance dose following a 900 mg loading dose of clopidogrel," said Professor Gilles Montalescot from the University Hospital Pitié-Salpêtrière, Paris, France.

The ACAPULCO crossover study was designed to compare the levels of platelet aggregation found in ACS patients receiving maintenance doses of either prasugrel (10 mg per day) or clopidogrel (150 mg per day), following a high loading dose of clopidogrel (900 mg).² Within 16 to 28 hours post loading dose, patients were randomly assigned to either a prasugrel 10 mg or clopidogrel 150 mg maintenance dose. After 14 days of their initial maintenance dose treatment, subjects were switched to the alternate study drug for 14 days.

The study showed that the 10 mg prasugrel dose produced a lower level of platelet aggregation compared to the 150 mg clopidogrel dose when both 14-day treatment periods were combined (26.2 percent vs. 39.1 percent, $p < 0.001$). The study also showed that, for patients initially treated with prasugrel, the 10 mg prasugrel dose achieved a lower level of platelet aggregation compared to the level observed 6-18 hours following the 900 mg clopidogrel loading dose (29.1 percent vs. 41.2 percent, $p < 0.003$). When these patients were crossed over to the 150 mg clopidogrel maintenance dose, platelet aggregation rose again to the level detected before prasugrel treatment.

1 The ACAPULCO Study: A Randomized, Double-Blind, Cross-Over Study Comparing the Pharmacodynamic Response in Subjects with Acute Coronary Syndrome Receiving 14 Days 10-mg Maintenance Dose Prasugrel (LY640315) versus 14 Days 150-mg Maintenance Dose Clopidogrel After Using a 900-mg Loading Dose of Clopidogrel to Reduce Ongoing Platelet Activation

2 In the French centers, where the study was conducted, a loading dose with 900 mg clopidogrel is used as the clinical standard for ACS patients who are to undergo PCI, an artery-opening procedure that often involves the use of a coronary stent to re-open a blocked artery.

Platelets play a significant role in ACS because they can form blood clots that can occlude coronary arteries, which may lead to subsequent cardiac events. Thus, antiplatelet agents that inhibit platelet activation and aggregation are necessary for the treatment of the acute event and subsequent maintenance therapy.³

More About the Study

The ACAPULCO study was a randomized, double-blind, crossover trial that compared the pharmacodynamic response of a 10 mg maintenance dose of prasugrel to that of a 150 mg clopidogrel dose in 56 patients treated with aspirin, following a 900 mg clopidogrel loading dose administered within 48 hours after UA/NSTEMI ACS symptoms.

About Prasugrel

Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) are co-developing prasugrel, an investigational oral antiplatelet agent invented by Daiichi Sankyo and its Japanese research partner Ube Industries, Ltd., as a potential treatment, initially for patients with acute coronary syndromes undergoing PCI. Prasugrel works by inhibiting platelet activation and subsequent aggregation by blocking the P2Y₁₂ adenosine diphosphate (ADP) receptor on the platelet surface. Antiplatelet agents prevent platelets from clumping or sticking together, which can result in clogged arteries and may lead to heart attack or stroke.

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 is cardiovascular disease, including therapies for dyslipidemia, hypertension, diabetes, and acute coronary syndrome. Equally important to the company is the discovery of new medicines in the areas of infectious diseases, cancer, bone and joint diseases, and immune disorders. For more information, visit www.daiichisankyo.com.

³ Bassand, JP, Hamm, C, et al. Guidelines for the diagnosis and treatment of non-ST-segment elevation acute coronary syndromes. European Heart Journal 2007; 28: 1616. Available at <http://www.escardio.org/admin/GuidelinesReferences/guidelines-NSTE-ACS-FT.pdf>. Accessed July 9, 2008.

Daiichi Sankyo, Inc. (www.dsus.com) headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Co., Ltd.

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.

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This press release contains certain forward-looking statements about the potential of the investigational compound prasugrel (CS-747, LY640315) and reflects Daiichi Sankyo’s and 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 approval, that the regulatory approval will be for the indication(s) anticipated by the companies, or that later studies and patient experience will be consistent with study findings to date. 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 and Daiichi Sankyo’s filings with the Tokyo Stock Exchange. Daiichi Sankyo and Lilly undertake no duty to update forward-looking statements.

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