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New Analysis Evaluated Impact of Genetic Variation on Response to Prasugrel

TOKYO AND INDIANAPOLIS, Ind. (May 5, 2009) – A new substudy from 1,466 patients from the Phase III TRITON-TIMI 38 clinical trial showed that patients who took prasugrel and had a reduced function of the CYP2C19 gene did not have an increased risk of cardiovascular death, heart attack or stroke compared with those patients who had normal function. The substudy results were published online in *Circulation* on May 4, 2009[1].

Prasugrel is a "prodrug" that requires the use of cytochrome P450 (CYP) enzymes to convert the drug into the active metabolite. Approximately 30 percent of Caucasians and 60 percent of Asians have reduced function in the

CYP2C19 gene, which is part of the CYP system and encodes the enzymes that are responsible for converting prasugrel into its active form[2].

In the substudy, researchers examined how variation in cytochrome P450 (CYP) genes affected the response to prasugrel. In prasugrel-treated patients with acute coronary syndromes (ACS) who underwent an artery-opening procedure known as percutaneous coronary intervention (PCI), the incidence of the combined endpoint of cardiovascular death, heart attack or stroke was 8.5 percent (N=407) in those who carried at least one variant in the CYP2C19 gene that reduced its function versus 9.8 percent (N=1048) in patients without a genetic variant (P=0.27). In addition, the rate of stent thrombosis in carriers of the reduced-function variant in the CYP2C19 gene compared with non-carriers treated with prasugrel was 0.5 percent vs. 1.0 percent, respectively (P=0.48). The results also showed that rates on non-CABG-related TIMI major or minor bleeding did not significantly differ by genetic variant among those treated with prasugrel.

“It is well documented in the medical literature that particular genetic variants in the CYP2C19 gene are associated with an increased risk of cardiovascular outcomes in patients treated with clopidogrel,” said Jessica Mega, M.D., M.P.H., Associate Physician at Brigham and Women's Hospital in Boston and Investigator at the TIMI Study Group. “We wanted to test if these genetic variants have a similar effect in patients who took prasugrel. Our findings showed that variation in the CYP2C19 gene did not appear to influence the rate of cardiac events in patients treated with prasugrel in this study.”

About the Genetic Analysis

This pre-specified analysis was designed to examine whether there is a genetic variation in DNA that could affect patient response to antiplatelet therapy. The pharmacogenetic analyses with prasugrel examined DNA samples from 1,466 patients from the TRITON-TIMI 38 clinical trial.

The genetic subanalysis was not powered to make efficacy comparisons between clopidogrel and prasugrel based on genetic variations.

The main TRITON-TIMI 38 clinical trial, previously published in the *New England Journal of Medicine* in November 2007 (Vol. 357 No.20), compared prasugrel with clopidogrel in patients with ACS undergoing PCI. In the primary analysis of the study, prasugrel reduced the risk of the combined endpoint of cardiovascular death, heart attack, or stroke by 19 percent (9.9 percent versus 12.1 percent), with an increased risk of major bleeding by 32 percent compared with clopidogrel (2.4 percent vs. 1.8 percent), which included life-threatening and fatal bleeding.[3]

About Acute Coronary Syndromes

Acute coronary syndromes, which is comprised of heart attacks and unstable angina (chest pain), affects nearly 1.5 million people in the United States annually.[4] Coronary heart disease, which can result in ACS, is the single most common cause of death in the European Union, accounting for more than 741,000 deaths in the EU each year.[5] Heart attack is a major manifestation of coronary heart disease, which occurs when the arteries become narrowed or clogged by cholesterol and fat deposits and cannot supply enough blood to the heart. In some cases, a blood clot may partially or totally block the blood supply to the heart resulting in ACS.[6] Many ACS patients are managed with PCI, which usually includes a stent placement.

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. Areas of focus for Daiichi Sankyo's research and development are cardiovascular disease, including therapies for dyslipidemia, hypertension, diabetes, and acute coronary syndromes. 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.

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.

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.

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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[2] Myrand SP, Sekiguchi K, Man MZ, Lin X, Tzeng RY, Teng CH, Hee B, Garrett M, Kikkawa H, Lin CY, Eddy SM, Dostalik J, Mount J, Azuma J, Fujio Y, Jang IJ, Shin SG, Bleavins MR, Williams JA, Paulauskis JD, Wilner KD. Pharmacokinetics/genotype associations for major cytochrome P450 enzymes in native and first- and third-generation Japanese populations: comparison with Korean, Chinese, and Caucasian populations. Clin Pharmacol Ther. 2008 Sep;84(3):347-61.

3 Wiviott, S, Braunwald, E, et al. Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes. New England Journal of Medicine. November 2007;357:2001-15.

4 American Heart Association. Heart Disease and Stroke Statistics – 2008 Update. http://www.americanheart.org/downloadable/heart/1200082005246HS_Stats%202008.final.pdf. Accessed August 13, 2008.

5 British Heart Foundation Health Promotion Research Group. European Cardiovascular Disease Statistics 2008, http://www.ehnheart.org/files/statistics%202008%20web-161229A.pdf, Accessed August 13, 2008.

6 WebMD Medical Reference in Collaboration with the Cleveland Clinic. Heart Disease: Coronary Artery Disease. http://www.webmd.com/heart-disease/guide/heart-disease-coronary-artery-disease. Accessed August 13, 2008.