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Prasugrel Significantly Reduced New or Recurrent Heart Attacks in Both Acute and Longer-Term Settings Following PCI, Compared with Clopidogrel

MUNICH, Germany (September 3, 2008) – A sub-analysis of the TRITON-TIMI 38 clinical trial showed that treatment with prasugrel compared with clopidogrel significantly reduced the risk of new or recurrent heart attacks (7.4 percent vs. 9.7 percent, $p < 0.0001$), regardless of whether the events occurred around the time of an artery-opening procedure known as percutaneous coronary intervention (PCI), or if they occurred spontaneously during the longer-term maintenance phase. The analysis was presented today at the European Society of Cardiology (ESC) in Munich, Germany.

The sub-analysis assessed the effect of prasugrel on new or recurrent heart attacks, occurring in the acute setting and during long-term medical treatment (up to 15 months) in 13,608 acute coronary syndromes (ACS) patients who were managed with PCI. New

or recurrent heart attacks were classified according to the ESC Universal Definition of Myocardial Infarction as spontaneous (Type 1) or procedure-related (Type 4 or 5).¹ The analysis showed that prasugrel consistently and significantly reduced spontaneous (Type 1) heart attacks by 29 percent compared with clopidogrel (2.5 percent vs. 3.4 percent, $p=0.0015$) and procedure-related recurrent heart attacks (Type 4 or 5) 24 percent in prasugrel-treated patients compared with those taking clopidogrel (4.9 percent vs. 6.4 percent, $p=0.0002$).

Long-term treatment with prasugrel, continuing after 30 days for up to 15 months, significantly reduced the risk for patients who suffer any form of heart attack by 23 percent compared with clopidogrel (2.9 percent vs. 3.7 percent, $p=0.01$). In the sub-analysis, prasugrel was also shown to reduce the risk of a future severe heart attack (ST elevation myocardial infarction (STEMI), a more severe form of ACS with a higher risk of death) by more than 50 percent compared with clopidogrel ($p=0.0001$).

The main TRITON-TIMI 38 clinical trial, for which overall results were previously published in the *New England Journal of Medicine* in November 2007 (Vol. 357 No.20), compared prasugrel with clopidogrel (Plavix[®]/Iscover[®]) in patients with ACS undergoing PCI. In the primary analysis of the trial, prasugrel reduced the risk of the composite of cardiovascular death, heart attack or stroke by 19 percent, with an increased risk of major bleeding compared with clopidogrel (2.4 percent vs. 1.8 percent).²

Heart attacks are a major manifestation of coronary heart disease, a global health problem. About 7.2 million people die each year from coronary heart disease worldwide.³ In the United States, the annual rate of heart attack is 920,000, with 600,000 being first-time attacks and 320,000 repeat attacks.⁴

"In this new sub-analysis of TRITON-TIMI 38, we found that the reduction of heart attacks seen with prasugrel compared with clopidogrel was consistent across the spectrum of heart attacks based on type, timing and magnitude," said David Morrow, M.D., M.P.H., associate professor of medicine at Harvard Medical School and the Brigham and Women's Hospital, Boston, USA, and investigator with the Thrombolysis in Myocardial Infarction (TIMI) Study Group.

About TRITON-TIMI 38

TRITON-TIMI 38 was a Phase III, randomized, double-blind, head-to-head clinical trial comparing the effects of prasugrel versus clopidogrel in patients with ACS who were managed with PCI, a procedure to open blockages in heart arteries including the use of coronary stenting. The study enrolled 13,608 patients at 707 trial sites in 30 countries.

The primary endpoint of the study was to compare the effects of prasugrel to clopidogrel on the combined incidence of cardiovascular death, non-fatal heart attack and non-fatal stroke during a median period of at least 12 months following PCI. Patients were randomly assigned to one of two treatment groups and given a loading dose of either prasugrel 60 mg or the approved loading dose of clopidogrel 300 mg anytime between randomization and one hour after the completion of the PCI procedure, followed by a daily maintenance dose of either prasugrel 10 mg or clopidogrel 75 mg. All patients also received a daily low dose of aspirin.

About Acute Coronary Syndromes

Acute coronary syndromes, which is comprised of heart attacks and unstable angina (chest pain), affects more than 1.4 million people in the United States annually.⁵ ACS, a fatal consequence of coronary heart disease, is the single most common cause of death in the European Union, accounting for more than 741,000 deaths in the EU each year.⁶ 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.⁷ 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 Company, Limited

Daiichi Sankyo Company, Limited, established in 2005 after the merger of two leading century-old Japanese pharmaceutical companies, is a global pharmaceutical innovator, continuously generating innovative drugs that enrich the quality of life for patients around the world. The company uses its cumulative knowledge and expertise in the fields of cardiovascular disease, cancer, metabolic disorders, and infection as a foundation for developing an abundant product lineup and R&D pipeline.

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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1 Type 1: Spontaneous myocardial infarction related to ischemia due to a primary coronary event

Type 2: Myocardial infarction secondary to ischemia due to either increased oxygen demand of the heart or decreased blood supply

Type 4/Type 5: Myocardial infarction associated with PCI/CABG

Thygesen K et al. Universal Definition of Myocardial Infarction. EHI(2007);28:2525-2538 <http://www.escardio.org/guidelines-surveys/esc-guidelines/GuidelinesDocuments/guidelines-universal-MI-FT.pdf>. Accessed August 13, 2008.

2 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.

3 World Health Organization. The Atlas of Heart Disease and Stroke - Deaths from Coronary Heart Disease.

http://www.who.int/cardiovascular_diseases/en/cvd_atlas_14_deathHD.pdf. Accessed August 13, 2008.

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 American Heart Association. Heart Disease and Stroke Statistics – 2008 Update.

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6 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.

7 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.