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In Landmark Phase III Head-to-Head Study, Prasugrel Statistically Superior to Clopidogrel in Reducing Risk of Heart Attack

Investigational compound reduces risk of major cardiovascular events by 19 percent, significantly improves net clinical benefit despite increased bleeding

TOKYO, Japan and INDIANAPOLIS, Ind. (Nov. 4, 2007) – In the pivotal Phase III head-to-head TRITON TIMI-38 clinical trial, the investigational antiplatelet agent prasugrel produced a highly significant 19 percent reduction in relative risk ($p=0.0004$) for the composite endpoint of cardiovascular death, non-fatal heart attack or non-fatal stroke when compared with clopidogrel (Plavix[®]/Iscover[®]) in the treatment of patients across the full spectrum of acute coronary syndrome undergoing percutaneous coronary intervention.

A significant reduction in the risk for the composite endpoint favoring prasugrel (60 mg loading dose/10 mg maintenance dose) over clopidogrel (300 mg LD/75 mg MD) was

observed as early as three days. The absolute difference in this endpoint continued to increase over the course of the 15-month, 13,608-patient trial.

In the important subgroup of patients with diabetes, prasugrel reduced the relative risk of cardiovascular death, non-fatal myocardial infarction and non-fatal stroke by 30 percent ($p<0.001$). In addition, in the key secondary endpoint of stent thrombosis, prasugrel reduced the recurrence of stent thrombosis (a new clot that develops at the stent site) by 52 percent ($p<0.0001$).

TRITON also showed that treatment with prasugrel significantly reduced the relative risk of cardiovascular death, non-fatal heart attack and non-fatal stroke by 21 percent in patients with STEMI (ST-elevation myocardial infarction, or high-risk heart attack) ($p=0.02$) and 18 percent in patients suffering from UA (unstable angina, or chest pain)/NSTEMI (non-STEMI) ($p=0.002$). In addition, prasugrel-treated patients experienced a 34 percent decline in urgent target vessel revascularization (a procedure to reopen blocked arteries) ($p<0.001$) and a 42 percent reduction in heart attack with subsequent death from cardiovascular causes ($p=0.02$).

While the overall incidence of non-CABG (coronary artery bypass grafting) bleeding in TRITON was low in both the prasugrel and clopidogrel treatment groups, prasugrel-treated patients experienced a statistically significant increase in non-CABG (coronary artery bypass grafting) major bleeding compared to clopidogrel-treated patients (2.4 vs. 1.8 percent, or 146 vs. 111 patients, $p=0.03$), including higher rates of life-threatening bleeding (1.4 vs. 0.9 percent, or 85 vs. 56 patients, $p=0.01$). Though infrequent, fatal bleeding was statistically more frequent among prasugrel-treated than clopidogrel-treated patients (0.4 percent vs. 0.1 percent, or 21 vs. five patients, $p=0.002$). However, death from cardiovascular causes occurred less frequently among prasugrel-treated patients than clopidogrel-treated patients (2.1 percent vs. 2.4 percent, or 133 vs. 150 patients, $p=0.31$), as did all-cause death (3.0 percent vs. 3.2 percent, or 188 vs. 197 patients, $p=0.64$).

The study identified three distinct patient subpopulations with a higher risk of major bleeding in both treatment arms – patients who were 75 years of age or older, weighed less than 60 kg (132 lbs.), or had a prior history of transient ischemic attack (TIA) or stroke. Researchers are evaluating pharmacokinetic data from several prasugrel studies, including TRITON, to determine whether a lower dose of prasugrel might be appropriate

for some patients. Among patients without any of these risk factors (80 percent of the 13,608-patient TRITON study), there was no significant difference in major bleeding between prasugrel- and clopidogrel-treated patients (2 percent vs. 1.5 percent, $p=0.17$).

Based on an analysis using the combined endpoint of all-cause death, heart attack, stroke and major bleeding, the net clinical benefit for prasugrel compared with clopidogrel was a significant 13 percent reduction in overall events (12.2 vs. 13.9, $p=0.004$). In the subpopulations defined as being at greater risk of bleeding, the net clinical benefit was not different between prasugrel- and clopidogrel-treated patients ($p=0.43$). Without the subpopulations defined as being at greater bleeding risk, the net clinical benefit was 20 percent (10.2 vs. 12.5, $p<0.001$).

Overall, for every 1,000 people treated with prasugrel compared to clopidogrel in the study, there were 23 fewer heart attacks and an additional six major bleeding complications.

"Our study provides compelling evidence that the prasugrel regimen tested is superior to standard dose clopidogrel as an antiplatelet therapy to support patients undergoing coronary stenting," said Elliott Antman, M.D., senior investigator with the TIMI Study Group at Harvard Medical School and director of the Samuel A. Levine Cardiac Unit at Brigham and Women's Hospital in Boston. "With the data from TRITON and other studies, we expect to define populations at particular bleeding risk to help establish clear guidance for using this promising therapy."

Antman announced the initial study results today at the American Heart Association's 2007 Scientific Sessions in Orlando, Florida (abstract 07-LBCT-20660-AHA). Prasugrel is being co-developed by Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY).

"The TRITON data demonstrate the statistical superiority of this new antiplatelet therapy to prevent heart attacks, and validate our decision to test prasugrel head to head against clopidogrel," said J. Anthony Ware, M.D., Lilly cardiovascular platform leader for prasugrel. "We are very pleased with the trial's outcome and are excited by the potential for these results to help us further tailor prasugrel therapy to assure the greatest benefit from this novel treatment."

Cardiovascular disease is the leading cause of death in the U.S. and worldwide, killing 16.7 million people each year.ⁱ Acute heart attacks and unstable angina, called acute coronary syndrome, affect more than 840,000 Americans each year and 800,000 in Europe.^{ii,iii} Utilizing current medical interventions and treatments, 300,000 people continue to experience recurrent heart attacks and 450,000 people die from heart attacks annually in the U.S.^{iv}

"TRITON confirms the statistically superior clinical benefit of prasugrel as a third-generation oral antiplatelet that may advance cardiovascular care," said John Alexander, M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited. "Given the promising TRITON results, Daiichi Sankyo and Lilly are expeditiously finalizing our submission package and are still hopeful to submit to the FDA by year end."

About the TRITON TIMI-38 study

TRITON TIMI-38 was a Phase III, multi-center, randomized, double blind, parallel group, head-to-head clinical trial comparing the effects of prasugrel versus clopidogrel in patients with acute coronary syndrome undergoing percutaneous coronary intervention (PCI). PCI is 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 composite incidence of cardiovascular death, non-fatal heart attack and non-fatal stroke during a median period of at least 12 months following PCI. Key secondary objectives included rehospitalization for a cardiac ischemic event; the need for additional procedures to restore blood flow (urgent target vessel revascularization) at 30 days; and stent thrombosis. Key safety endpoints included non-CABG major, life threatening and minor bleeding as well as the overall safety and tolerability of prasugrel.

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.

Antiplatelet agents are critical for both acute and maintenance therapy to inhibit platelet activation and subsequent aggregation that occur in diseased arteries and as adjunct therapy to invasive procedures such as percutaneous coronary intervention.

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 syndrome 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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ⁱ World Health Organization. The Atlas of Heart Disease and Stroke - Types of Cardiovascular Disease 2005.

ⁱⁱ American Heart Association. Heart Disease and Stroke Statistics - 2006 Update. Dallas, TX. American Heart Association.

ⁱⁱⁱ Bertrand CURE study

^{iv} American Heart Association. Heart Attack and Angina Statistics. URL: <http://www.americanheart.org/presenter.jhtml?identifier=4591>. Last accessed July 26, 2007.