



Mortality Data Presented for Patients Treated with Effient® Who Underwent Isolated Coronary Artery Bypass Surgery

CHICAGO, Nov. 16, 2010 /PRNewswire-FirstCall/ -- New results from an observational substudy from TRITON—TIMI 38 presented today at the American Heart Association (AHA) Scientific Sessions annual meeting showed that patients treated with Effient® (prasugrel) prior to coronary artery bypass graft surgery (CABG) had a reduced overall mortality rate compared to patients treated with Plavix® (clopidogrel) (2.3 percent versus 8.7 percent respectively, $p=0.016$).⁽¹⁾

This retrospective analysis involved 346 patients with acute coronary syndrome (ACS) who had received either study drug and subsequently underwent isolated CABG at some point during the 15-month TRITON-TIMI 38 trial.⁽²⁾

In addition to all-cause mortality, this same analysis found that the risk-adjusted rate of cardiovascular death at 30 days was also lower in patients treated with Effient compared with those receiving clopidogrel (0.6 percent versus 5.8 percent respectively, $p=0.038$).⁽³⁾ Effient-treated patients experienced a statistically significantly higher volume of chest tube blood loss at 12 hours post-CABG compared to the clopidogrel-treated patients (655 +/- 580 milliliters with Effient versus 503 +/- 378 milliliters with clopidogrel).⁽¹⁾

"This analysis showed that Effient was associated with a significantly lower mortality rate compared with clopidogrel among these CABG patients but with a significantly higher risk of serious bleeding events," said Peter K. Smith, M.D., professor of surgery and division chief of Cardiovascular and Thoracic Surgery at Duke University Medical Center and lead investigator for the retrospective CABG analysis. "This analysis helps better define the risk of mortality for physicians who care for the ACS patients who may be targeted for percutaneous coronary intervention (PCI) but end up undergoing CABG instead."

The Effient prescribing information includes a warning and precaution against starting Effient in patients likely to undergo urgent CABG surgery. The risk of bleeding is increased in patients receiving Effient who undergo CABG. If possible, Effient should be discontinued at least seven days prior to CABG.⁽⁴⁾

Study Methodology

TRITON-TIMI 38 was a Phase III, randomized, double-blind, head-to-head clinical trial comparing the effects of Effient 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 the combined incidence of cardiovascular death, non-fatal heart attack or non-fatal stroke during at least 12 months following PCI. Patients were randomly assigned to one of two treatment groups and given a loading dose of either Effient 60 mg or the FDA-approved loading dose of clopidogrel 300 mg, followed by a daily maintenance dose of either Effient 10 mg or clopidogrel 75 mg. All patients also received a daily dose of aspirin (75 mg to 325 mg).

This retrospective analysis included newly collected data on 346 patients who underwent isolated CABG following withdrawal of study drug, either Effient ($n=173$) or clopidogrel ($n=173$), during the TRITON-TIMI 38 study.⁽²⁾ Possible baseline imbalances between arms were adjusted using European System for Cardiac Operative Risk Evaluation (EuroSCORE) and Society of Thoracic Surgeons (STS) scoring, two widely accepted and standardized methods of calculating cardiac operative mortality risk.⁽²⁾ Bleeding was measured by chest tube blood loss, a standard method used by surgeons.⁽²⁾ Despite the adjustment for predicted risk of mortality at the time of CABG, this non-randomized comparison between Effient and clopidogrel may be subject to potential residual biases.⁽²⁾

About Effient

Daiichi Sankyo Company, Limited (TSE: 4568), and Eli Lilly and Company (NYSE: LLY) co-developed Effient, an oral antiplatelet agent discovered by Daiichi Sankyo and its Japanese research partner, Ube Industries, Ltd. Effient helps keep blood platelets from clumping together and developing a blockage in an artery. Effient is approved by the U.S. Food and Drug Administration for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with ACS who are managed with an artery-opening procedure known as PCI. PCI usually includes the placement of a stent to help keep the artery open.

About Acute Coronary Syndromes

ACS, which includes heart attack and unstable angina (chest pain), affects more than 1.5 million people in the United States annually, many of whom are managed with PCI.(5) In 2010, an estimated 785,000 people in the United States will have a new heart attack, and about 470,000 will have a recurrent attack.(6) ACS results in significant morbidity and mortality, accounting for half of all deaths due to cardiovascular disease, and costs Americans more than \$150 billion annually, nearly 60 percent of which results from rehospitalization.(7)

Important Safety Information about Effient

Antiplatelet medicines, including Effient, can increase a patient's risk of bleeding. If patients have unexplained or excessive bleeding while on Effient, they should contact their doctor right away as some bleeding can be serious, and sometimes may lead to death. Patients should not take Effient if they have a stomach ulcer or other conditions that cause bleeding or if they have a history of stroke or "mini-stroke" (transient ischemic attack or TIA).

If patients are 75 or older, or if they weigh less than 132 pounds, or if they are taking anticoagulants (e.g., warfarin) or taking NSAIDs (e.g., ibuprofen or naproxen) for a long time, they should talk to their doctor, as they may be at an increased risk of bleeding.

Patients should not stop taking Effient without first talking to the doctor who prescribed it for them, as this may result in increased risk of a clot in their stent, a heart attack or death.

Patients should get medical attention right away if they develop any of the following unexpected symptoms: fever, weakness, yellowing of the skin or eyes, or if skin becomes very pale or dotted with purple spots. These symptoms may be signs of a rare but potentially life-threatening condition called TTP, sometimes after a short time (less than 2 weeks).

For more information about Effient, please see the Full Prescribing Information, including Boxed Warning (<http://pi.lilly.com/us/effient.pdf>), and Medication Guide (<http://pi.lilly.com/us/effient-ppi.pdf>). You may also learn more about Effient at www.Effient.com.

About Daiichi Sankyo

The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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. Additional information about Lilly is available at www.lilly.com.

This press release contains certain forward-looking statements about Effient for the reduction of thrombotic cardiovascular events (including stent thrombosis) in patients with acute coronary syndromes who are managed with percutaneous coronary intervention and reflects Daiichi Sankyo's and Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that future study results and patient experience will be consistent with study findings to date or that the product will 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.

Effient® is a registered trademark of Eli Lilly and Company.

Plavix® is a registered trademark of Sanofi-Aventis Corp.

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(1) Smith PK, Despotis GJ, Goodnough LT, Levy, J, Poston, R, Short, M, et al. Mortality benefit with prasugrel in TRITON-TIMI 38 coronary artery bypass grafting (CABG) cohort: Risk adjusted retrospective data analysis. Abstract presented at: 2010 American Heart Association Scientific Sessions; November 2010; Chicago, IL.

(2) Smith PK, Despotis GJ, Goodnough LT, Levy, J, Poston, R, Short, M, et al. Mortality benefit with prasugrel in TRITON-TIMI 38 coronary artery bypass grafting (CABG) cohort: Risk adjusted retrospective data analysis. Study presented at: 2010 American Heart Association Scientific Sessions; November 2010; Chicago, IL.

(3) Data on File at Eli Lilly and Company. Coronary Artery Bypass Grafting Cardiovascular Death Data Table.

(4) Effient Full Prescribing Information

(5) American Heart Association. Heart Disease and Stroke Statistics — 2008 Update. Dallas, TX. American Heart Association. (Pg. 14).

(6) American Heart Association Heart Disease and Stroke Statistics — 2010 Updated. Dallas, TX. American Heart Association. (Pg. e86).

(7) Kolansky, D. Acute coronary syndromes: Morbidity, mortality, and pharmacoeconomic burden. Amer J of Managed Care, 2009;15:S36-S41. http://www.ajmc.com/media/pdf/A213_09mar_KolanskyS36to41.pdf. Last accessed October 19, 2010.

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