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Phase II study showed switching ACS-PCI patients to Effient®/aspirin from Plavix®/aspirin regimen reduced maximum platelet aggregation after one week

PARSIPPANY, N.J. and INDIANAPOLIS (September 14, 2010) – A study evaluating the level of platelet aggregation achieved after switching from Plavix® (clopidogrel) 75 mg once-daily maintenance dosing plus aspirin to Effient® (prasugrel) 10 mg once-daily maintenance dosing (MD) in patients with acute coronary syndrome (ACS) was published today in the *Journal of the American College of Cardiology*. In this Phase II study, ACS patients who were switched to Effient (either 10 mg maintenance dose [MD] or 60 mg loading dose [LD] followed by 10 mg MD) plus aspirin demonstrated a statistically significant greater reduction in Maximum Platelet Aggregation (MPA) after one week when compared with patients who remained on maintenance therapy with clopidogrel. The Switching Anti Platelet Study (SWAP) was sponsored by Daiichi Sankyo Co., Ltd. and Eli Lilly and Company.

Platelet aggregation is a critical step in the formation of blood clots, which pose a significant risk to patients following an ACS event, including heart attack and heart-related chest pain. The study provides further evidence to suggest that Effient reduces platelet aggregation to a greater extent among ACS patients compared to Plavix.

Of the 128 patients who completed the study, 100 patients were eligible to be included in the platelet function analysis. After a 10-14 day run-in phase with open label clopidogrel 75 mg once daily plus aspirin, patients were randomly assigned to one of the following three treatments: remain on clopidogrel 75 mg plus aspirin for 7 days (n=33); switch to prasugrel 10 mg plus aspirin for 7 days (n=36); or switch to prasugrel 60 mg loading dose plus aspirin followed by prasugrel 10 mg plus aspirin daily for 6 days (n=31).

At day 7, MPA (as measured using 20 μM ADP) was statistically significantly lower in patients switched to prasugrel 10 mg plus aspirin when compared with the patients who remained on clopidogrel (41.1 percent vs. 55.0 percent, $p<0.0001$) and in those patients switched to prasugrel 60 mg LD followed by prasugrel 10 mg MD vs. clopidogrel (41.0 percent vs. 55.0 percent, $p<0.0001$).

“These findings are important because they provide new insights into potential differences in the levels of platelet inhibition that can be achieved with dual oral antiplatelet therapy in patients with ACS,” said Dominick J. Angiolillo, M.D., assistant professor, Department of Medicine, Division of Cardiology, University of Florida College of Medicine, Jacksonville, and lead author of the paper. “The data showed that Effient plus aspirin may provide additional reduction in platelet aggregation in ACS patients over those taking standard-dose clopidogrel plus aspirin. However, a larger study would be needed to assess the potential impact of switching on cardiovascular outcomes.”

The SWAP study was not designed to evaluate efficacy or safety endpoints.

Study Methodology

SWAP was a Phase II, multicenter, randomized, double-blind, double-dummy, active-controlled trial evaluating the effects on platelet function after switching patients on daily clopidogrel therapy following an ACS event to daily Effient therapy. Patients were eligible for enrollment if they were between 18 and 75 years of age, presented 30 to 330 days after an ACS event and treated with daily aspirin and clopidogrel. They were excluded if they had any of the following: a planned coronary revascularization procedure (coronary artery bypass surgery or coronary angioplasty) during the study, high risk of bleeding, history of stroke or mini stroke, or weight of less than 60 kg.

Platelet function was evaluated at 2 hours, 24 hours, 7 days and 14 days using three different tests, including light transmittance aggregometry, the standard way to measure platelet aggregation.

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 indicated to reduce the risk of future heart-related events, such as heart attack or blood clot in a stent, in patients with ACS managed with a procedure called angioplasty.

About Acute Coronary Syndrome

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.[1] In 2009, an estimated 785,000 people in the United States were predicted to have a new heart attack, and about 470,000 were predicted to have a recurrent attack.[2] 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.[3]

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

[2] American Heart Association Heart Disease and Stroke Statistics – 2009 Updated. Dallas, TX. American Heart Association. (Pg. 2)

[3] Kolansky, D, Acute coronary syndromes: Morbidity, mortality, and pharmacoeconomic burden. Amer J of Manag Care, 2009;15:S36-S41. http://www.ajmc.com/media/pdf/A213_09mar_KolanskyS36to41.pdf Accessed Feb. 12, 2010.