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Effient® Exhibited Greater Antiplatelet Activity than High Dose Clopidogrel in Type 2 Diabetes Mellitus Patients with Coronary Artery Disease

ORLANDO, Fla. (Nov. 15, 2009) – Results from a new study showed patients with type 2 diabetes mellitus who also had coronary artery disease (CAD) and received a 60 mg loading dose and 10 mg maintenance dose of Effient® (prasugrel) achieved significantly greater platelet inhibition compared with a 600 mg loading dose and 150 mg maintenance dose of Plavix® (clopidogrel). These data were presented today at the American Heart Association 2009 Scientific Sessions.

The OPTIMUS-3 study, which evaluated 35 patients with type 2 diabetes who also had CAD and were taking aspirin, showed that within four hours, the level of platelet inhibition as measured using the VerifyNow® P2Y12 Test with a 60 mg loading dose of Effient was higher than observed with a 600 mg loading dose of

clopidogrel (89 percent vs. 28 percent inhibition of platelet activation [IPA], respectively; *P*<0.0001). In addition, one hour after the loading dose, patients who received Effient had 50 percent IPA compared with 13 percent in patients who received clopidogrel. The level of platelet inhibition achieved for each drug at four hours was unchanged over the following 24 hours. A 600 mg loading dose of clopidogrel is not currently approved for use.

“Previous research has shown that patients with type 2 diabetes mellitus have more active platelets, so might be more prone to clotting, than non-diabetics, and may have suboptimal response to therapies that reduce platelet activity,” said Dominick Angiolillo, M.D., Ph.D., assistant professor of Medicine and director of Cardiovascular Research, Division of Cardiology, University of Florida, Jacksonville, Fla. “This study was designed to compare the antiplatelet activity of prasugrel (Effient) used at standard doses with high doses of clopidogrel (Plavix) in patients with type 2 diabetes mellitus who also had coronary artery disease.”

The study also looked at the maintenance doses of Effient and clopidogrel. After seven days, results showed that a 10 mg maintenance dose of Effient achieved greater platelet inhibition than a 150 mg maintenance dose of clopidogrel (62 percent vs. 44 percent IPA, respectively; P<0.0001).

This study was performed in patients who did not have a specific indication for clopidogrel therapy (more than 12 months after an acute coronary event or bare metal stent placement and no drug eluting stent in place). The relationship between inhibition of platelet aggregation and clinical activity has not been established.

About OPTIMUS-3

OPTIMUS-3 (Third **O**ptimizing anti-**P**latelet **T**herapy **I**n Diabetes **M**ellit**US**) evaluated the pharmacodynamic effects of Effient compared with clopidogrel in 35 patients with type 2 diabetes mellitus who also had CAD and were taking

aspirin. The double-blind crossover study compared loading and maintenance doses of Effient (60 mg and 10 mg, respectively) with a higher 600 mg loading dose and a higher 150 mg maintenance dose of clopidogrel for one week, followed by a 14-day washout period before patients crossed over to receive the alternate study drug.

Measurements of platelet inhibition were taken at several time periods, including baseline, one hour, four hours and 24 hours post loading dose, as well as six to eight days post maintenance dose during each period of the study. Inhibition of platelet aggregation was measured using three separate methods: VerifyNow P2Y12 assay, light transmission aggregometry, and phosphorylation of vasodilator stimulated phosphoprotein.

About Type 2 Diabetes Mellitus in Patients with Coronary Artery Disease

At least 65 percent of people with diabetes mellitus eventually will die of some form of heart or blood vessel disease.[1] CAD is the major cause of mortality and morbidity in patients with type 2 diabetes mellitus.[2]

CAD is the chronic narrowing or hardening of the coronary arteries and is a condition linked to acute coronary syndromes (ACS). Over time, plaques build up in the arteries of patients with CAD. If a plaque ruptures and a clot forms in the artery, it may suddenly block blood supply to the heart, a condition known as ACS.[3]

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 percutaneous coronary intervention (PCI). PCI usually includes the placement of a stent to help keep the artery open.

Important Safety Information about Effient

Antiplatelet medicines, including Effient, can increase the 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 (eg, warfarin) or taking NSAIDs (eg, ibuprofen or naproxen) for a long time, they should talk to their doctor, as they may be at an increased risk of bleeding.

If patients plan to have surgery or a dental procedure, they should tell their doctors that they are taking Effient.

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, which has been reported with other medicines in this class that are like Effient, sometimes after a short time (less than 2 weeks).

For more information about Effient including prescribing information, please visit www.Effient.com.

About Daiichi Sankyo

A global pharmaceutical 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 primary focus for Daiichi Sankyo research and development are thrombotic disorders, malignant neoplasm, diabetes mellitus, and autoimmune disorders. Equally important to the company are hypertension, hyperlipidemia or atherosclerosis and bacterial infections. 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.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.

VerifyNow® is a registered trademark of Accumetrics.

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[1] American Heart Association. Diabetes Mellitus-Statitics-2009 Update. http://www.americanheart.org/downloadable/heart/1236357007811FS12DIAB08.pdf

[2] Young, L, Cardiac Outcomes After Screening for Asymptomatic Coronary Artery Disease in Patients With Type 2 Diabetes: The DIAD Study: A Randomized Controlled Trial. JAMA, 2009;301(15):1547-1555.

[3] Cleveland Clinic. Understanding Coronary Artery Disease. Available at: http://my.clevelandclinic.org/heart/disorders/cad/understandingcad.aspx. Last accessed on Oct. 29, 2009.