Date: October 23, 2012

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New Retrospective Studies of Hospital Readmission Rates for Subsequent Heart Attack and Initial Hospitalization Costs in ACS-PCI Patients Treated with Effient® (Prasugrel) or Plavix® (Clopidogrel) Presented at TCT

MIAMI, October 23, 2012 – Daiichi Sankyo, Inc. and Eli Lilly and Company (NYSE: LLY) today announced new results of two retrospective, observational comparative effectiveness studies of U.S. hospital data comparing rates of readmission for subsequent heart attack and initial hospitalization costs among patients with acute coronary syndromes (ACS) treated with a percutaneous coronary intervention (PCI) and antiplatelet therapy, including Effient® (prasugrel) or Plavix® **(**clopidogrel). The findings were presented at the 24th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF),

TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine.

The first study evaluated the rate of rehospitalization for acute myocardial infarction (AMI) and bleeding at both 30- and 90-days after discharge for ACS-PCI patients treated with Effient compared to Plavix.[1] Based on a cohort of 83,567 ACS-PCI patients in the PREMIER database, Effient-treated patients (n=9,404) had a significantly lower adjusted rate of rehospitalization for AMI than Plavix-treated patients (n=74,163) at 30 days (Odds Ratio [OR]: 0.89; p=0.047) and 90 days (OR: 0.90; p= 0.037) following ACS-PCI discharge. The adjusted rates of bleeding-related rehospitalization were not different between Effient- and Plavix-treated patients at 30 days (OR: 1.04; p=0.82) or 90 days (OR: 0.92; p=0.51) post-discharge. In the pivotal randomized control trial, TRITON-TIMI 38, the risk of serious bleeding was significantly higher with Effient versus Plavix (2.2 percent versus 1.7 percent, respectively).[2]

The second study evaluated use of healthcare resources by Effient-treated ACS-PCI patients compared to Plavix-treated patients during index hospitalization (hospitalization that qualified the patients for entry into the study), as measured by hospital costs.[3] Based on a cohort of 84,695 ACS-PCI patients in the PREMIER database, adjusted estimates of average hospitalization costs for patients receiving Plavix (n=75,224) or Effient (n=9,471) were $17,519 (±$2,548) and $17,139 (± $2,560) respectively – a cost savings of $380 ($p<0.05$) for Effient-treated patients during the index hospital stay. Results were consistent across subgroups by subtype of ACS (STEMI, NSTEMI, and unstable angina).

"In the current healthcare environment, it is important to understand the comparative effectiveness of antiplatelet therapies on rehospitalization rates for subsequent events, such as heart attacks, and index hospitalization costs associated with their use in the real-world setting," said lead study investigator Jay P. Bae, Ph.D., health economist, Health Outcomes Research, Global Health Outcomes, Eli Lilly and Company. "The

findings of these studies expand on data from clinical studies and previous health outcomes research."

The studies were conducted using the PREMIER Perspective Database, a large U.S. database of drug utilization and other aggregate hospital data on more than 45 million inpatient discharges and 210 million hospital outpatient visits from U.S. acute care facilities, ambulatory surgery centers and clinics.[4] The PREMIER Perspective Database has been selected by the Centers for Medicare & Medicaid Services for measurement of hospital quality and is commonly used for outcomes research including studies published in top medical journals. The data presented at TCT evaluated non-randomized ACS-PCI patients hospitalized between July 2009 and June 2011. The study endpoints were pre-specified and the analyses were blinded and conducted by the PREMIER research team. The studies included ACS-PCI patients treated with Effient who were on label or Plavix-treated patients who would have been eligible for Effient treatment per the U.S. prescribing information (i.e., patients who fit the description of the indication in the U.S. FDA-approved Effient label).[1]

"The results from the PREMIER studies provide physicians with real-world insights into the use and effectiveness of Effient in ACS-PCI patients in the United States," said Xin Ye, Ph.D., Director, Health Economics & Outcomes Research, Daiichi Sankyo, Inc.

This study was adjusted for potential selection bias, including the following variables: patient age, sex, race, type of ACS diagnosis, comorbidities and details of intervention.

The studies were conducted by researchers at Lilly and the Premier Healthcare Alliance.

Assessment of Observed Rates of 30-and 90-Day Rehospitalization for AMI and Bleeding in Patients with ACS-PCI: Comparison of Effient and Plavix

The observed rates of 30 and 90-day rehospitalization due to AMI and 30- and 90-day bleeding-related rehospitalization rates among ACS-PCI patients treated with Effient or Plavix in a real-world U.S. hospital setting were also presented at TCT. At 30-days, the unadjusted AMI-related rehospitalization rates were significantly lower for Effient as compared to Plavix (3.9 percent and 4.7 percent, respectively; $p<0.05$). At 90-days, the unadjusted AMI-related rehospitalization rates were significantly lower for Effient as compared to Plavix (5.1 percent and 6.3 percent, respectively; $p<0.05$).

The unadjusted bleeding-related rehospitalization rate was 0.5 percent in Effient-treated patients compared to 0.8 percent in Plavix-treated patients at 30-days ($p<0.05$) and 0.8 percent in Effient-treated patients compared to 1.4 percent in Plavix-treated patients at 90-days ($p<0.05$) post-discharge.

Observed Mean Length of Stay, Hospitalization Costs and Bleeding Rates of ACS-PCI: Comparison of Effient and Plavix

The goal of this analysis was to compare observed mean length of stay, total costs and bleeding rates associated with the index hospitalization – hospitalization that qualified the patients for entry into the study – for ACS-PCI patients treated with Effient or Plavix. Across the entire study population, the unadjusted mean length of stay was 2.9±2.4 days for Effient-treated patients as compared to 3.5±4.4 days for Plavix-treated patients ($p<0.05$). The actual observed mean hospitalization costs for Effient-treated patients were $16,199± $10,054 compared to $17,647± $16,696 for Plavix-treated patients ($p<0.05$).

In the study, unadjusted rates of bleeding (defined as the presence of bleeding ICD-9 codes) were 2.2 percent and 3.3 percent in Effient- and Plavix-treated patients, respectively ($p<0.05$).

Unadjusted rates of transfusion were 1.2 percent and 3.1 percent in Effient- and Plavix-treated patients, respectively ($p<0.05$). Unadjusted rates of bleeding or transfusion were 3.2 percent and 5.7 percent in Effient- and Plavix-treated patients, respectively ($p<0.05$).

In the pivotal randomized control trial, TRITON-TIMI 38, the risk of serious bleeding was significantly higher with Effient versus Plavix (2.2 percent versus 1.7 percent, respectively).[2]

Limitations of the PREMIER Database Studies

Although significant demographic, clinical, treatment- and intervention-related data were used to adjust for potential bias in these studies, other unrecognized sources of bias may still exist in any non-randomized database study. For example, the PREMIER database did not include data on patient characteristics, such as blood pressure, height and weight. The lack of weight data is important, since weight is a predictor of risk for bleeding. The researchers plan to conduct additional quantitative analysis on potential sources of bias in the database.

About Acute Coronary Syndrome

ACS, which includes heart attack and a type of chest pain called unstable angina (UA), affects more than one million people in the United States annually.[5] The annual incidence of new heart attacks is estimated to be approximately 610,000 and about 325,000 people will have a recurrent attack. There are two main types of heart attack: non-ST-segment elevation, or NSTEMI, and ST-segment elevation, or STEMI. STEMI heart attacks are often considered more severe as the artery is often fully blocked, preventing blood flow to the heart.

Each year, approximately 596,000 people undergo PCI, which typically includes the implantation of a stent that restores blood flow to blocked arteries in the heart. The number of UA or NSTEMI ACS patients worldwide who are managed without acute

coronary interventions, such as PCI, has ranged from 32 percent to almost 60 percent over the last few years.[6,7] In many cases, these ACS patients may have complex coronary anatomy, comorbidities or other high-risk factors that prevent surgical intervention.

ACS may result in heart attack, stroke and death, costing Americans more than $150 billion each year.[8] Nearly 60 percent of the U.S healthcare costs of ACS are due to re-hospitalization. Strategies to prevent recurrent heart attacks and re-hospitalization are important to improve patient outcomes and reduce the cost burden of ACS.

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 rate of thrombotic CV events (including stent thrombosis) in patients with ACS who are to be managed with an artery-opening procedure called PCI as follows: [1] patients with UA or NSTEMI; [2] patients with ST-elevation myocardial infarction (STEMI) when managed with primary or delayed PCI. The loading dose of Effient is 60 mg and the maintenance dose is 10 mg once daily. Effient is available in 5-mg and 10-mg tablets.

Important Safety Information

What is the most important information patients should know about Effient?

Effient® (prasugrel) can cause 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 fatal. Patients should not take Effient if they currently have abnormal bleeding, such as stomach or intestinal bleeding, bleeding in their head, or have a history of stroke, or "mini-stroke" (also known as transient ischemic attack or TIA), or are allergic to prasugrel or any of the ingredients in Effient.

Patients should get medical help right away if they suddenly have slurring of speech, weakness or numbness in one part of their body, blurry vision, and/or severe headache. These may be symptoms of a stroke or TIA. If patients have a stroke or TIA while taking Effient, their doctor will probably stop Effient.

Before having any surgery, patients should talk to their doctor about stopping Effient. If possible, patients should stop taking Effient at least 1 week (7 days) before any surgery, as instructed by their doctor who prescribed Effient.

Patients may also have a higher risk of bleeding if they take Effient and they: a) are age 75 or older, b) weigh less than 132 pounds, c) are taking anticoagulants (eg, warfarin) or regular daily use of NSAIDs, d) have had recent trauma, such as an accident or surgery, e) have severe liver problems, or f) have a stomach ulcer.

Patients should not stop taking Effient without talking to the doctor who prescribes it for them. People who are treated with angioplasty and have a stent, and stop taking Effient too soon, have a higher risk of a blood clot in the stent, having a heart attack, or dying.

What should patients tell their doctor before taking Effient?

Patients should tell their doctor about all of their medical conditions, allergies, and medicines they are taking.

What are the possible side effects of Effient?

Bleeding is the most common side effect of Effient.

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

Serious allergic reactions can happen with Effient, or if the patient has had a serious allergic reaction to the medicines Plavix® (clopidogrel) or ticlopidine. Patients should get

medical help right away if they get any of these symptoms of a severe allergic reaction: swelling or hives of their face, lips, in or around their mouth, or throat, trouble breathing or swallowing, chest pain or pressure, dizziness or fainting.
Other side effects may occur.

For more information about Effient, please see the Prescribing Information at http://pi.lilly.com/us/effient.pdf, including Boxed Warning regarding bleeding risk, and Medication Guide at 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.

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[1] Bae JP, Faries DE, Ernest FR et al. Assessment of 30-Day Rehospitalization for Acute Myocardial Infarction in Patients with Acute Coronary Syndrome Who Received Percutaneous Coronary Intervention: A Comparative Effectiveness Study of Clopidogrel and Prasugrel. Abstract TCT-53. 2012 Transcatheter Cardiovascular Therapeutics Annual Meeting, Miami, FL.

[2] Effient Prescribing Information (U.S.).

[3] Bae JP, Ernst FR, Lipkin C, et al. Hospitalization Costs of Acute Coronary Syndrome Patients Undergoing Percutaneous Coronary Intervention: A Comparison Between Clopidogrel and Prasugrel Patients in a US Hospital Database. Abstract 730. 2012 Transcatheter Cardiovascular Therapeutics Annual Meeting, Miami, FL.

[4] Premier Research Services®. https://www.premierinc.com/prs/index.jsp.

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[7] Chan MY, Mahaffey KW, Sun LJ, et al. Prevalence, predictors, and impact of conservative medical management for patients with non-ST-segment elevation acute coronary syndromes who have angiographically documented significant coronary disease. *J Am Coll Cardiol.* 2008;1:369-378.

[8] Kolansky DM. Acute coronary syndromes: Morbidity, mortality and pharmacoeconomic burden. *Am J Manag Care*. 2009;15:S36-S41.