Effient® Added to Updated ACCF/AHA Clinical Guidelines for ACS-PCI Patients with Unstable Angina and Non-ST Segment Myocardial Infarction

PARSIPPANY, N.J. and INDIANAPOLIS, March 29, 2011 /PRNewswire/ -- Oral antiplatelet therapy Effient® (prasugrel) has been added to the updated clinical practice guidelines as a Class I recommended treatment option for patients undergoing percutaneous coronary intervention (PCI) after experiencing heart-related chest pain at rest (unstable angina) or non-ST segment elevation myocardial infarction (NSTEMI). NSTEMI is a type of heart attack that that does not need to be treated with emergent opening of a blocked coronary artery.(1) The update to the clinical guidelines, jointly developed by the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA), was published online on March 28, 2011, in the *Journal of the American College of Cardiology* and *Circulation*.

"Class I" means that a given "procedure/treatment should be performed/administered" to patients, given it was found to be "useful/effective/beneficial." Class I is the highest recommendation provided by the guidelines committee.

Effient tablets are approved by the U.S. Food and Drug Administration to reduce the risk of future heart-related events, such as heart attack or stent thrombosis, in patients with acute coronary syndromes (ACS) who are treated with PCI. ACS includes heart attack and unstable angina (UA).

The guidelines also include the following recommendations for the use of Effient:

- Patients with UA or NSTEMI who are at medium to high risk and will have a PCI may be treated with aspirin and Effient at the time of PCI. (Class I recommendation)
- Patients with UA or NSTEMI who undergo PCI and prescribed Effient should remain on 10 mg of Effient plus aspirin for at least 12 months. (Class I recommendation)
- A loading dose of 60 mg of Effient may be considered for administration promptly as pre-treatment for a UA/NSTEMI patient for whom PCI is planned, the bleeding risk is low and coronary artery bypass graft surgery is unlikely. (Class IIb recommendation, which means treatment may be considered)
- Consistent with the U.S. Effient label, the new UA/NSTEMI guidelines provide a Class III recommendation to avoid the use of Effient plus aspirin in patients with a prior history of TIA or stroke as part of a dual-antiplatelet therapy regimen.

"The guidelines committee has now classified Effient with a Class I recommendation for a larger population of ACS-PCI patients, including those with unstable angina, severe and non-severe heart attacks -- all of whom may be at increased risk of future cardiovascular events after undergoing coronary intervention," said Paul Vaitkus, M.D., senior medical director, thrombosis, Daiichi Sankyo, Inc. "The guidelines are now in line with the FDA-approved labeling for Effient."

"The new guidelines issued by the ACCF and AHA recognize Effient as an important treatment option for the population of ACS patients who receive PCI with or without a stent after experiencing unstable angina or NSTEMI, which is a type of heart attack that that does not need to be treated with emergent opening of a blocked coronary artery," said LeRoy LeNarz, MD, senior medical director, Cardiovascular, Eli Lilly and Company. "This updated clinical guidance offers alternative treatment options for cardiologists when they are considering appropriate oral antiplatelet therapy for patients with different forms of ACS."

In November 2009, Effient also was added as a Class I recommended treatment in AHA/ACC/SCAI clinical guidelines for patients with UA or NSTEMI receiving PCI and for patients with ST elevation myocardial infarction (STEMI), which is a severe heart attack.

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 Syndrome

ACS, which includes heart attack and a type of chest pain called unstable angina, affects more than one million people in the United States annually.(2) In 2010, an estimated 610,000 Americans had a new heart attack, and about 325,000 had a recurrent attack.(2) Each year, approximately 645,000 people with ACS are managed with PCI, which typically includes the implantation of a stent that restores blood flow to blocked arteries in the heart.(3) ACS results in significant illness and death, costing Americans more than $150 billion each year.(3) Nearly 60 percent of the U.S. healthcare costs of ACS are due to re-hospitalization.(3) Strategies to prevent recurrent heart attacks and re-hospitalization are important to improve patient outcomes and reduce the cost burden of ACS.(3)

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" (transient ischemic attack or TIA). Patients should stop taking Effient if they have a stroke.

Whenever possible, patients should stop taking Effient at least 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 NSAIDs (eg, ibuprofen or naproxen) for a long time, d) undergo surgery, or e) have severe liver problems.

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?

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 potentially 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.

Other side effects may occur.

For more information about Effient, please see the Full Prescribing Information at http://pi.lilly.com/us/effient.pdf, including Boxed Warning 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. P-LLY

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) American Academy of Family Physicians, American College of Emergency Physicians, Society for Cardiovascular Angiography and Interventions and Society of Thoracic Surgeons. R. Scott Wright, Jeffrey L. Anderson, Cynthia D. Adams, et al. *J. Am. Coll. Cardiol.* Published online Mar 28, 2011; doi:10.1016/j.jacc.2011.02.009.

2011 ACCF/AHA Focused Update of the Guidelines for the Management of Patients With Unstable Angina/Non—ST-Elevation Myocardial Infarction (Updating the 2007 Guideline): A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines

(2) Roger VL, Go AS, Lloyd-Jones DM, et al. for the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics — 2011 update. *Circulation*. 2011;123:e1-e192.

(3) Kolansky DM. Acute coronary syndromes: morbidity, mortality, and pharmacoeconomic burden. *American Journal of Managed Care*. 2009;15:S36-S41.

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