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New 2016 ACC/AHA Guideline Focused Update States that it is Reasonable to Choose Effient® (prasugrel) Over Clopidogrel for Certain ACS-PCI Patients with ST-Elevation Myocardial Infarction and NSTE-ACS

Class IIa recommendation provided for maintenance use of Effient in ACS-PCI STEMI and NSTE-ACS patients who are not at high risk for bleeding complications and who do not have a history of stroke or transient ischemic attack

PARSIPPANY, N.J. and INDIANAPOLIS (March 31, 2016) – A new guideline focused update provided oral antiplatelet therapy Effient® (prasugrel) with a Class IIa recommendation, meaning that it is reasonable to choose Effient over clopidogrel for the maintenance therapy of patients with acute coronary syndrome (ACS) who experience an ST-elevation myocardial infarction (STEMI) – the most severe form of a heart attack[1] – or non–ST-segment elevation (NSTE) who are treated with dual antiplatelet therapy (DAPT) after percutaneous coronary intervention (PCI). This recommendation applies to patients who are not at a high risk for bleeding complications and do not have a prior history of stroke or transient ischemic attack (TIA).

The 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy (aspirin and oral antiplatelet therapy) in Patients with Coronary Artery Disease, jointly developed by the American College of Cardiology (ACC) and American Heart Association

(AHA), was published online ahead of print in the *Journal of the American College of Cardiology* and *Circulation*.

Effient is indicated to reduce the rate of thrombotic cardiovascular (CV) events (including stent thrombosis) in patients with ACS who are to be managed with PCI as follows: [1] patients with unstable angina (UA) or non–ST-elevation myocardial infarction (NSTEMI); [2] patients with STEMI when managed with primary or delayed PCI. Effient can cause significant, sometimes fatal, bleeding. Do not use Effient in patients with active pathological bleeding or a history of transient ischemic attack or stroke. Overall rates of major or minor bleeding were significantly higher with Effient plus aspirin (ASA) compared with clopidogrel plus ASA in the TRITON-TIMI 38 trial. Effient is available in 5-mg and 10-mg tablets. See the Important Safety Information, including Boxed Warnings, at the bottom of this press release and the Full Prescribing Information.

"The ACC/AHA guideline provided a Class IIa recommendation to Effient, meaning it is reasonable to choose Effient over clopidogrel for the maintenance treatment of STEMI and NSTE-ACS patients who have undergone a PCI procedure to open a blocked artery," said Howard Rutman, vice president, Medical Affairs, Daiichi Sankyo, Inc. "The updated guideline reinforces the important role of Effient maintenance therapy in reducing the risks of recurrent heart events and stent thrombosis in the appropriate patients who are not at high risk for bleeding complications and who do not have a prior history of stroke or TIA."

In addition, Effient has again received a Class I recommendation (Level of Evidence: B-R) for the maintenance treatment of at least 12 months for patients with ACS (STEMI or NSTE-ACS) treated with DAPT after stent (bare metal or drug-eluting) implantation.

"The ACC/AHA maintained the highest recommendation (Class I) that for ACS-PCI patients treated with DAPT after stent (BMS or DES) implantation, Effient should be given for at least 12 months, which reflects the strong clinical data we have from the landmark TRITON-TIMI 38 trial," said Nayan Acharya, senior medical director, Cardiovascular, Dermatology and Inflammation, Lilly USA, LLC. "The guideline provides clarity to physicians evaluating the optimal choice of oral antiplatelet treatment options for STEMI

and NSTE-ACS patients who are particularly at risk for stent thrombosis and recurrent heart events following PCI."

Consistent with the Effient label, the new ACC/AHA guideline focused update again provides a Class III: Harm recommendation that Effient should not be administered to patients with a history of prior stroke or TIA.

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. Approved by the U.S. Food and Drug Administration in July 2009, 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 lead to death. 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 if they 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 moderate to severe kidney problems, or g) have a stomach ulcer.

Patients should call their doctor right away if they have any of these signs or symptoms of bleeding: unexpected bleeding or bleeding that lasts a long time, bleeding that is severe or they cannot control, pink or brown urine, red or black stool, bruises that happen without a known cause or get larger, cough up blood or blood clots or vomit blood or their vomit looks like coffee grounds.

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.

Effient is available by prescription only. For more information, patients should talk to their healthcare provider or pharmacist.

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Patients can visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information about Effient, please click here for the Full Prescribing Information, including Boxed Warning regarding bleeding risk, and Medication Guide.

About Acute Coronary Syndrome (ACS)

ACS, which includes heart attack and a type of chest pain called unstable angina (UA), was responsible for the hospitalization of more than one million people in the United States in 2010.[2] The annual incidence of new heart attacks is estimated to be approximately 660,000 and about 305,000 will have a recurrent attack.[2] 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. Almost 250,000 Americans experience STEMI each year.[1]

People with ACS may undergo an angioplasty procedure, known as a percutaneous coronary intervention (PCI), to open a blocked coronary artery. According to AHA's *Heart Disease and Stroke Statistics—2016 Update*, in 2010, an estimated 492,000 patients underwent PCI in the United States.[2]

ACS may result in heart attack, stroke 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. Strategies to prevent recurrent heart attacks and re-hospitalization are important to improve patient outcomes and reduce the cost burden of ACS.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 17,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to its strong portfolio of medicines for hypertension, dyslipidemia, bacterial infections, and thrombotic disorders, the Group's research and development is focused on bringing forth novel therapies in cardiovascular-metabolic diseases, pain management, and oncology, including biologics. For more information, please visit: www.daiichisankyo.com.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and newsroom.lilly.com/social-channels.
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This press release contains certain forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995 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. Among other things, there is no guarantee that future study results or 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 most recent Form 10-K and Form 10-Q filings 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 to reflect events after the date of this release.

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

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[1] STEMI Systems of Care. American Heart Association website. http://www.heart.org/HEARTORG/HealthcareResearch/MissionLifelineHomePage/LearnAboutMissionLifeline/STEMI-Systems-of-Care_UCM_439065_SubHomePage.jsp. Updated 2015. Accessed April 6, 2016.

[2] Go AS, Mozaffarian D, Roger VL, et al. for the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics – 2016 update. Circulation. Published online December 16, 2015.

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