



New Analysis Showed Effient(R) Cost-Effective Compared with Clopidogrel for Patients with Acute Coronary Syndromes Undergoing PCI

PARSIPPANY, N.J. and INDIANAPOLIS, Jan 05, 2010 /PRNewswire-FirstCall via COMTEX News Network/ -- Results from a health economic substudy of the TRITON-TIMI 38 clinical trial showed that among patients with acute coronary syndromes (ACS) managed with percutaneous coronary intervention (PCI), including stenting, treatment with Effient((R)) (prasugrel) compared with branded clopidogrel (Plavix((R))) was more cost effective, and in most cases cost saving. These results were published in *Circulation* on January 5, 2010.(1)

In the pre-specified analysis of 6,705 patients, treatment with Effient compared with clopidogrel reduced total hospitalization costs over approximately 15 months, not including the cost of study drugs, by \$530 per patient. This cost offset estimate includes bleeding-related costs that a sensitivity analysis showed were not a major driver of the overall cost difference between the two treatments.

The analysis also found that, including cost of the active study drugs as well as costs associated with the initial and subsequent hospitalizations, treatment with Effient compared with clopidogrel decreased cumulative medical costs by \$221 per patient over the 14.7-month study. Study drug costs used in the analysis were the net wholesale price as of August 2009, which was \$5.45 per day for Effient and \$4.62 per day for clopidogrel.

"Results of the cost-effectiveness analysis showed that treatment with Effient was highly cost effective and an economically dominant option compared with Plavix," said David J. Cohen, M.D., M.Sc., director of cardiovascular research, Saint Luke's Mid America Heart Institute and professor of medicine, University of Missouri-Kansas City. "These favorable results were found in an analysis that considered only the first 30 days of treatment, as well an analysis that considered the time period starting from 31 days through the rest of the follow-up period. These analyses are important because the results provide the healthcare community, including formulary decision makers, with new data regarding the cost-effectiveness of Effient for patients with ACS undergoing PCI."

"Dominant" is a health economics term used when a new treatment yields greater clinical effectiveness at lower costs. In TRITON-TIMI 38, Effient plus aspirin (ASA) was shown to significantly reduce the rate of a combined endpoint of cardiovascular death, nonfatal heart attack, or nonfatal stroke compared to clopidogrel plus ASA. In addition, patients treated with Effient also had significantly fewer stent thromboses (stent-related blood clots) compared to those treated with clopidogrel. These benefits were accompanied by a significantly higher risk of bleeding, which in some cases were life-threatening or even fatal in patients treated with Effient compared with clopidogrel.

The analysis also compared Effient to generic clopidogrel at a hypothetical cost of \$1 per day. When compared to clopidogrel at this lower cost, treatment with Effient in the subpopulation as a whole was economically dominant (e.g., cost saving) during the first 30 days of treatment. After day 31, although not cost-saving, it continued to be a cost-effective therapy relative to many other accepted medical interventions.

"The hypothetical comparison with generic clopidogrel is important because the patent exclusivity for Plavix will expire in 2011 or 2012. Results from this comparison to generic clopidogrel will be useful information for the medical community, especially payers, in the future," said Dr. Cohen, "and suggest that the overall benefit of Effient was still favorable relative to its higher cost in this setting."

Study Methodology

TRITON-TIMI 38 was a Phase III, randomized, double-blind, head-to-head clinical trial comparing the effects of Effient versus clopidogrel in patients with ACS who were managed with PCI, a procedure to open blockages in heart arteries, including the use of coronary stenting. The study enrolled 13,608 patients at 707 trial sites in 30 countries.

The primary endpoint of the study was the combined incidence of cardiovascular death, non-fatal heart attack or non-fatal stroke during a median period of at least 12 months following PCI. Patients were randomly assigned to one of two treatment groups and given a loading dose of either Effient 60 mg or the FDA-approved loading dose of clopidogrel 300 mg, followed by a daily maintenance dose of either Effient 10 mg or clopidogrel 75 mg. All patients also received a daily dose of aspirin (75 mg to 325 mg).

The economic analysis was completed using data from 6,705 study patients enrolled in eight pre-specified countries, including the United States, Australia, Canada, France, Germany, Italy, Spain and United Kingdom. The primary economic measure was total in-trial costs including hospitalization and medication costs. The approach to estimating costs was to multiply counts of resource use (hospitalizations, physician costs, procedures, medications) by price weights derived from comparable populations of US patients. All costs other than study drug costs were assessed in 2005 US dollars.

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 US 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.

About Acute Coronary Syndromes

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.(2) In 2009, an estimated 785,000 people in the United States will have a new heart attack, and about 470,000 will have a recurrent attack.(3) 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.(4)

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((R)) is a registered trademark of Eli Lilly and Company.

Plavix((R)) is a registered trademark of Sanofi-Aventis Corp.

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(Logo: <http://www.newscom.com/cgi-bin/prnh/20061120/DSLLOGO>)

(1) Mahoney EM, Wang K, et al. Cost-Effectiveness of Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes and Planned PCI: Results from the TRITON-TIMI 38 Trial. *Circulation*. 2010; 121: 71-79.

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

(3) American Heart Association Heart Disease and Stroke Statistics - 2009 Updated. Dallas, TX. American Heart Association. (Pg. 2)

(4) Kolansky, D, Acute coronary syndromes: Morbidity, mortality, and pharmaco-economic burden. *Amer J of Manag Care*, 2009;15:S36-S41. http://www.ajmc.com/media/pdf/A213_09mar_KolanskyS36to41.pdf. Accessed Oct. 13, 2009.

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