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Multiple Types of Heart Attacks Reduced by Prasugrel in TRITON-TIMI 38 Trial

Universal Definition of Myocardial Infarction provided jointly by leading international cardiology societies

TOKYO AND INDIANAPOLIS, Ind. (May 21, 2009) – Investigators from the Phase III TRITON-TIMI 38 study applied the new classification system for the Universal Definition of Myocardial Infarction to the results of the study and showed that patients with acute coronary syndromes (ACS) undergoing percutaneous coronary intervention (PCI) and taking prasugrel, as compared with patients taking clopidogrel (Plavix®/Iscover®), experienced reduced risk of heart attack regardless of heart-attack type (procedural related or spontaneous), size or timing over a 15-month period. The new Universal Definition of Myocardial Infarction[1] was developed in 2007 by the Joint European Society of Cardiology, American College of Cardiology, American Heart Association and the World Heart Federation Task Force. This post hoc analysis was published in *Circulation* online on May 18, 2009.[2]

In this post hoc analysis, the incidence of non-procedural heart attack in patients treated with prasugrel compared with patients treated with clopidogrel was 2.8 percent vs. 3.7 percent, respectively (p=0.0013). The risk of procedure-related heart attacks was 4.9 percent in patients who took prasugrel compared with 6.4 percent in patients who took clopidogrel (p=0.0002). Non-procedure-related heart attacks included spontaneous heart attacks, which could be differentiated from procedure-related heart attacks that were associated with the artery-opening procedure known as PCI, or with stent thrombosis.

The analysis reported in this paper was not pre-specified in the TRITON-TIMI 38 study because the Universal Definition of Myocardial Infarction was published after the trial started.

“Our findings provide a more complete characterization of the effect of prasugrel on new or recurrent heart attacks,” said David A. Morrow, M.D. M.P.H., Associate Professor of Medicine at Harvard Medical School and a Senior Investigator with the TIMI Study Group, Cardiovascular Division, Department of Medicine, Brigham and Women’s Hospital, Boston, MA.

Investigators classified 1,218 heart attacks that occurred during the TRITON-TIMI 38 study based on the Universal Definition of Myocardial Infarction. This definition includes a new classification system to characterize different types of heart attacks based on the size and type of heart attack.[3] The types of heart attacks evaluated in this study, according to the definition, included:

- Type 1: Spontaneous heart attack caused by a primary coronary event, such as a plaque rupture in a coronary artery with less blood then flowing to the muscle
- Type 2: Secondary heart attack due to either increased oxygen demand or decreased supply due to other conditions such as spasm of the coronary artery or low blood oxygen from anemia
- Type 3: Sudden cardiac death with evidence of a heart attack
- Type 4: Heart attacks related to a PCI
    - Type 4a: Heart attacks associated with a PCI procedure
    - Type 4b: Heart attacks associated with stent thrombosis as documented by an angiography or at autopsy
- Type 5: Heart attack associated with coronary artery bypass graft (CABG).

The investigators examined the size and timing of a new heart attack, as well as whether or not the heart attack was associated with an elevation of the ST segment on the electrocardiogram (noted as STEMI and NSTEMI).

The results of the analysis showed:

- The rate of spontaneous heart attacks (Type 1) was 2.5 percent in patients taking prasugrel compared with 3.4 percent in those taking clopidogrel (p=0.0015).
- The incidence of PCI-related heart attacks (Type 4) was 4.8 percent in prasugrel patients compared with 6.4 percent in clopidogrel patients (p=0.0002).
- The majority of spontaneous heart attacks occurred after 30 days of treatment, and the risk of non-procedural heart attack during maintenance dosing through the entire 15 months of the study was 2.3 percent in patients taking prasugrel versus 3.1 percent in patients taking clopidogrel (p=0.0069).
- Treatment with prasugrel reduced new and recurrent STEMI heart attacks, a high-risk form of heart attack (1.0 percent vs. 2.1 percent, p<0.0001), and NSTEMI heart attacks (6.5 percent vs. 7.9 percent, p=0.0024) compared with clopidogrel.
- In the TRITON-TIMI 38 trial, there was an increased risk of major bleeding with prasugrel by 32 percent compared with clopidogrel (2.4 percent vs. 1.8 percent), which included life-threatening and fatal bleeding.[4]

About TRITON-TIMI 38

The main TRITON-TIMI 38 clinical trial, previously published in the *New England Journal of Medicine* in November 2007 (Vol. 357 No.20), compared prasugrel with clopidogrel in patients with ACS undergoing PCI. In the primary analysis of the study, prasugrel reduced the risk of the combined endpoint of cardiovascular death, heart attack, or stroke by 19 percent (9.9 percent versus 12.1 percent), with an increased risk of major bleeding by 32 percent compared with clopidogrel (2.4 percent vs. 1.8 percent), which included life-threatening and fatal bleeding.[5]

About Acute Coronary Syndromes

Acute coronary syndromes (ACS), which includes heart attack and unstable angina (chest pain), affects more than 1.4 million people in the United States

annually.[6] Coronary heart disease, which can result in ACS, is the single most common cause of death in the European Union, accounting for more than 741,000 deaths in the EU each year.[7] Coronary artery disease occurs when the arteries become narrowed or clogged by cholesterol and fat deposits and cannot supply enough blood to the heart. In some cases, a blood clot may partially or totally block the blood supply to the heart, resulting in ACS.[8] Many ACS patients are managed with PCI, which usually includes a stent placement.

About Prasugrel

Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) are co-developing prasugrel, an investigational oral antiplatelet agent invented by Daiichi Sankyo and its Japanese research partner Ube Industries, Ltd., as a potential treatment, initially for patients with acute coronary syndrome undergoing PCI. Prasugrel works by inhibiting platelet activation and subsequent aggregation by blocking the P2Y12 adenosine diphosphate (ADP) receptor on the platelet surface. Antiplatelet agents prevent platelets from clumping or sticking together, which can result in clogged arteries and may lead to heart attack or stroke.

About Daiichi Sankyo

A global pharmaceutical innovator, Daiichi Sankyo Company, 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 central 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 Company, 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 first-in-class and best-in-class 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.

This press release contains certain forward-looking statements about the potential of the investigational compound prasugrel (CS-747, LY640315) and reflects Daiichi Sankyo's and Lilly's current beliefs. However, as with any pharmaceutical compound under development, there are substantial risks and uncertainties in the process of development and regulatory review. There is no guarantee that the compound will receive anticipated regulatory approvals, that the regulatory approvals will be for the indication(s) anticipated by the companies, or that later studies and patient experience will be consistent with study findings to date. There is also no guarantee that the compound will prove to 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 Thygesen K, Alpert JA, White HD, et al. Universal Definition of Myocardial Infarction. Circulation 2007;116:2634-2653.

2 Effect of the Novel Thienopyridine Prasugrel Compared with Clopidogrel on Spontaneous and Procedural Myocardial Infarction in the TRITON-TIMI 38 Trial: an Application of the Universal Definition of Myocardial Infaction. Cardiology. Circulation. June 2, 2009.

3 Thygesen K, Alpert JA, White HD, et al. Universal Definition of Myocardial Infarction. Circulation 2007;116;2634-2653.

4 Wiviott, S, Braunwald, E, et al. Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes. New England Journal of Medicine. November 2007;357:2001-15.

5 Ibid

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7 British Heart Foundation Health Promotion Research Group. European Cardiovascular Disease Statistics 2008, http://www.ehnheart.org/content/ItemPublication.asp?docid=7069&level0=1500&level1=2157, Accessed April 24 2008.

8 WebMD Medical Reference in Collaboration with the Cleveland Clinic. Heart Disease: Coronary Artery Disease. June 2004.