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## **Prasugrel Receives Unanimous Approval Recommendation from FDA Advisory Committee**

**TOKYO, Japan, and INDIANAPOLIS, IN (February 3, 2009)** – The U.S. Food and Drug Administration Cardiovascular and Renal Drugs Advisory Committee voted 9 to 0 that prasugrel, an investigational antiplatelet agent should be approved for the treatment of patients with acute coronary syndromes (ACS) managed with an artery-opening procedure known as percutaneous coronary intervention (PCI), Daiichi Sankyo Company, Limited, (TSE: 4568), and Eli Lilly and Company (NYSE: LLY) announced today.

The Advisory Committee voted unanimously that prasugrel should be approved for the treatment of patients with acute coronary syndromes undergoing PCI. The FDA is not bound by the committee's recommendation, but it takes its advice into consideration when reviewing new drug applications.

“We are very proud of the prasugrel data, including the data presented at the hearing,” said John Alexander M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited. “Today’s scientific exchange set the stage for a potential FDA approval of prasugrel, and the future availability of this significant scientific advancement for the treatment of ACS-PCI patients.”

“We will continue to work closely with the FDA as the agency moves toward an action on the new drug application for prasugrel,” said J. Anthony Ware, M.D., Lilly vice president and cardiovascular/acute care platform leader for prasugrel. “It is important for patients to have multiple treatment options, and currently, ACS patients undergoing PCI have few options. Today’s vote by the advisory committee members is a positive step for patients.”

“Prasugrel represents an important new option for patients with ACS who are managed with PCI,” said lead TRITON-TIMI 38 investigator Elliott Antman, M.D., director of the Samuel A. Levine Cardiac Unit at Brigham and Women’s Hospital (BWH) in Boston and senior investigator with BWH’s TIMI Study Group. “In a large head-to-head trial, TRITON, showed that prasugrel was superior to clopidogrel, the current standard of care. While the benefit of prasugrel is accompanied by an increased risk of serious bleeding events, appropriate selection of patients and doses may help mitigate this risk.”

The committee reviewed comprehensive data primarily from the TRITON TIMI-38 clinical trial. Results from the TRITON trial showed that prasugrel taken with aspirin reduced the relative risk of the combined endpoint of cardiovascular death, non-fatal heart attacks or non-fatal stroke by 19 percent more than clopidogrel (Plavix<sup>®</sup>/Iscover<sup>®</sup>) taken with aspirin. These benefits were accompanied by an increased risk of serious bleeding with prasugrel overall, some of which included life-threatening and even fatal bleeding. When the risk of this type of bleeding was compared to the benefit of reduced heart attack, there were five more TIMI major bleeding events, but 22 fewer heart attacks for every 1,000 patients treated with prasugrel compared to every 1,000 patients treated with clopidogrel.<sup>1</sup> The overall risk of cardiovascular death and the risk of increased stroke were not statistically different between treatment groups.

FDA reviewers will consider the panel's favorable recommendation in its review of the new drug application that Lilly submitted for prasugrel on behalf of the alliance with Daiichi Sankyo, Limited, on December 26, 2007.

### **The Burden of 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.<sup>ii</sup> 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.<sup>iii</sup> 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.<sup>iv</sup> 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 discovered by Daiichi Sankyo and its Japanese research partner, Ube Industries, Ltd., as a potential treatment, initially for patients with acute coronary syndrome who are managed with PCI. Prasugrel works by inhibiting platelet activation and subsequent aggregation by blocking the P2Y<sub>12</sub> 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 pharma 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. A central focus of Daiichi Sankyo's 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](http://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.dsus.com](http://www.dsus.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.

*Plavix®/Iscover® is a registered trademark of Sanofi Aventis Corp.*

### **P-LLY**

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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 regulatory approval, that the regulatory approval 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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<sup>i</sup> 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.

<sup>ii</sup> American Heart Association. Heart Disease and Stroke Statistics – 2008 Update. Dallas, TX. American Heart Association. (Pg. 14)

<sup>iii</sup> 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.

<sup>iv</sup> WebMD Medical Reference in Collaboration with the Cleveland Clinic. Heart Disease: Coronary Artery Disease. June 2004.