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**European Commission Approves EFIENT<sup>®</sup> (prasugrel)  
for Patients with Acute Coronary Syndrome Undergoing PCI**

TOKYO, Japan, and INDIANAPOLIS, Ind. (February 23, 2009) – Heart patients with acute coronary syndrome (ACS) undergoing an artery-opening procedure will soon have a new treatment option to help prevent heart attacks. Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) announced today that the European Commission has granted marketing authorization for EFIENT<sup>®</sup> (pronounced Ef-ee-ent) (prasugrel) for the prevention of atherothrombotic events in patients with ACS undergoing percutaneous coronary intervention (PCI).

The approval follows a positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency on December 18, 2008.

“This European approval is good news for doctors and patients since more than 700,000 people die from heart attacks in the European Union each year,” said Takashi Shoda, president and chief executive officer of Daiichi Sankyo Co., Ltd. “We believe Efient will become an important new

treatment for patients with ACS undergoing PCI, a severe disease with potentially life-threatening consequences."

Prasugrel works by reducing the tendency of platelets, the blood particles responsible for clotting, from sticking or clumping together. By blocking a specific receptor (P2Y12 adenosine diphosphate) on the platelet surface, prasugrel prevents platelets from clumping, which can result in clogged arteries and may lead to heart attack.

"The approval of Effient helps to meet an important medical need. Survivors of heart attacks have a substantial risk of suffering from one or more additional heart attacks," said John C. Lechleiter, Ph.D., chairman, president and chief executive officer of Lilly. "This action is a major step forward in giving healthcare professionals and patients in European countries a new antiplatelet option for treating ACS."

In a large Phase III study, prasugrel was superior to Plavix<sup>®</sup>/Iscover<sup>®</sup> (clopidogrel) in reducing the risk of suffering major cardiovascular events (combined endpoint of cardiovascular death, non-fatal heart attack or non-fatal stroke) in ACS patients undergoing PCI. The risk of non-coronary artery bypass graft (non-CABG) major bleeding, including fatal bleeding, was higher with prasugrel (2.2 percent incidence) compared with clopidogrel (1.7 percent incidence). Compared with the overall study population, a higher risk of serious bleeding among prasugrel patients was most evident in three distinct patient populations that are readily identifiable: patients who weighed less than 60 kg (132 lbs), patients who were 75 years of age or older and patients who have had a prior transient ischemic attack (TIA) or stroke. Patients who weighed less than 60 kg, or were 75 years of age or older had increased exposure with prasugrel.

The U.S. Food and Drug Administration is evaluating whether prasugrel should be approved in the United States for the treatment of patients with acute coronary syndromes (ACS) managed with percutaneous coronary intervention (PCI). The proposed name for prasugrel in the US is Effient<sup>™</sup>.

Daiichi Sankyo Company, Limited, and Eli Lilly and Company co-developed prasugrel, an oral antiplatelet agent discovered by Daiichi Sankyo and its Japanese research partner Ube Industries,

Ltd. (TSE:4208) as a treatment initially for patients with acute coronary syndromes who are undergoing PCI.

### **About Acute Coronary Syndrome**

Acute coronary syndrome includes heart attacks and unstable angina (chest pain). 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>1</sup> In addition, ACS affects nearly 1.5 million people in the United States annually.<sup>2</sup> Heart attack is a major manifestation of coronary heart disease, which occurs when the arteries become narrowed or clogged by cholesterol and fat deposits. In some cases the plaque can rupture, resulting in a blood clot, which may partially or totally block the blood supply to portions of the heart, resulting in ACS.<sup>3</sup> Many ACS patients undergo PCI to re-open the artery, which usually includes a stent placement.

### **About Daiichi Sankyo**

A global pharma 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. 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 Co., 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.

*This press release contains certain forward-looking statements about the potential of prasugrel (CS-747, LY640315) and reflects Daiichi Sankyo's and Lilly's current beliefs. However, as with any pharmaceutical compound, there are substantial risks and uncertainties in the process of development, regulatory review, and commercialization. There is no guarantee that the compound will receive 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.*

*Plavix<sup>®</sup>/Iscover<sup>®</sup> are registered trademarks of sanofi-aventis.*

*Efient<sup>®</sup> is a registered trademark of Eli Lilly and Company.*

*Effient<sup>™</sup> is a trademark of Eli Lilly and Company.*

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1 British Heart Foundation Health Promotion Research Group. European Cardiovascular Disease Statistics 2008, <http://www.ehnheart.org/files/statistics%202008%20web-161229A.pdf>, Accessed December 9, 2008.

2 American Heart Association. Heart Disease and Stroke Statistics – 2008 Update. [http://www.americanheart.org/downloadable/heart/1200082005246HS\\_Stats%202008.final.pdf](http://www.americanheart.org/downloadable/heart/1200082005246HS_Stats%202008.final.pdf). Accessed December 9, 2008.

3 WebMD Medical Reference in Collaboration with the Cleveland Clinic. Heart Disease: Coronary Artery Disease. <http://www.webmd.com/heart-disease/guide/heart-disease-coronary-artery-disease>. Accessed December 9, 2008.