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### **FDA Cardio Renal Advisory Committee to Review Daiichi Sankyo, Lilly Drug Prasugrel**

**TOKYO, Japan, and INDIANAPOLIS, IN (December 31, 2008)** – Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) today confirmed that the U.S. Food and Drug Administration's (FDA) Cardiovascular and Renal Drugs Advisory Committee (CRDAC) will review prasugrel during an advisory committee hearing on February 3, 2009. Prasugrel is an investigational antiplatelet agent for the treatment of patients with acute coronary syndromes (ACS) who are being managed with an artery-opening procedure known as percutaneous coronary intervention (PCI), which is usually followed by the placement of a stent to help keep the artery open.

Advisory committees provide the FDA with independent advice from outside medical experts during the review process. The companies will have further discussions with the FDA in preparation for the Advisory Committee Meeting.

“We welcome the opportunity to discuss any and all of the prasugrel data with the advisory committee and the agency, just as we have throughout the ongoing review,” said John Alexander M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited.

“We have full confidence in the data submitted to the FDA and the overall benefit-risk profile of prasugrel, and we look forward to this next step in potentially bringing an important new alternative to the oral antiplatelet market,” said J. Anthony Ware, M.D., Lilly vice president and cardiovascular/acute care platform leader for prasugrel.

### **The Burden of Acute Coronary Syndromes**

Acute coronary syndromes (ACS), which is comprised of heart attacks and unstable angina (chest pain), affects more than 1.4 million people in the United States annually.<sup>i</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>ii</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>iii</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 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.

### **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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i American Heart Association. Heart Disease and Stroke Statistics – 2008 Update. Dallas, TX. American Heart Association. (Pg. 14)

ii 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

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