

For Immediate Release  
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**FDA grants priority review for Daiichi Sankyo, Lilly drug, prasugrel**

*Investigational antiplatelet agent submitted for treatment of patients with acute coronary syndrome being managed with percutaneous coronary intervention*

The attached is the co-press release with Eli Lilly and Company, which was issued in US on February 21, 2008.



**Date: February 21, 2008**

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## **FDA grants priority review for Daiichi Sankyo, Lilly drug, prasugrel**

***Investigational antiplatelet agent submitted for treatment of patients with acute coronary syndrome being managed with percutaneous coronary intervention***

TOKYO, Japan, and INDIANAPOLIS, Ind. (February 21, 2008) – Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) accepted and designated Priority Review for the New Drug Application for prasugrel, for patients with acute coronary syndrome being managed with percutaneous coronary intervention (PCI). The NDA for prasugrel was submitted to the agency on Dec. 26, 2007.

A priority designation by the FDA sets the PDUFA (Prescription Drug User Fee Act) goal date. The PDUFA goal for priority applications is to have an action provided for 90 percent of applications within six months. FDA can take three different actions – approved, approvable with further discussion, or not approved.

"We are greatly pleased to learn that the FDA has determined the application meets its criteria for such a review, and we look forward to working with the agency as it continues its review process," said Dr. J. Anthony Ware, Lilly vice president for cardiovascular/acute care.

"If approved, prasugrel will provide physicians and acute coronary syndrome patients an alternative medicine that may further help reduce the risk of heart attacks," said John Alexander, M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Ltd.

### **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 Company, Limited**

Daiichi Sankyo Company, Limited, established in 2005 after the merger of two leading century-old Japanese pharmaceutical companies, is a global pharmaceutical innovator, continuously generating innovative drugs that enrich the quality of life for patients around the world. The company uses its cumulative knowledge and expertise in the fields of cardiovascular disease, cancer, metabolic disorders, and infection as a foundation for developing an abundant product lineup and R&D pipeline.

### **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

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.