

For Immediate Release

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**Daiichi Sankyo and Lilly Respond to Speculation  
On Status of Prasugrel New Drug Application**

The attached is the co-press release with Eli Lilly and Company, which was issued on October 16, 2008. (US time)



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**Daiichi Sankyo and Lilly Respond to Speculation  
On Status of Prasugrel New Drug Application**

TOKYO, Japan, and INDIANAPOLIS, Ind. (October 16, 2008) – In response to recent media speculation regarding the status of the prasugrel new drug application (NDA), Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) reiterated today that they continue to have discussions with the FDA regarding the review of this application. The companies have not been notified of any regulatory action for the new drug application (NDA) or of any decision to have an advisory committee to review prasugrel. 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.

“Daiichi Sankyo and Lilly are engaged in an ongoing dialogue with the FDA,” said Jennifer Stotka, M.D., Lilly vice president of Global Regulatory Affairs. “We remain confident in the overall benefit-risk profile of prasugrel, and we believe this drug should

be approved so that we can bring this valuable treatment option to ACS patients, a population at risk for further cardiovascular events.”

“The FDA can schedule an Advisory Committee at any time during the review of an application. If one is called, then we will be prepared to participate,” said John Alexander, M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited.

Lilly, on behalf of its alliance partner, Daiichi Sankyo, submitted a new drug application to the FDA for prasugrel in December 2007. Lilly, on behalf of the alliance, also submitted a Marketing Authorization Application for prasugrel to the European Medicines Agency in February 2008.

In the TRITON-TIMI 38 clinical trial of more than 13,000 patients, the primary measure 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 may be life threatening. Overall, for every 1,000 people treated, there were six more TIMI major bleeding events, but 23 fewer heart attacks in patients taking prasugrel compared with patients taking clopidogrel.<sup>i</sup> The risk of cardiovascular death overall in the study was not statistically different between treatment groups [prasugrel (2.0%) compared with clopidogrel (2.2%)].

#### **About Daiichi Sankyo Company, Limited**

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 is cardiovascular disease, including therapies for dyslipidemia, hypertension, diabetes, and acute coronary syndrome. Equally important to the company is the discovery of new medicines in the areas of infectious diseases, cancer, bone and joint diseases, and immune disorders. For more information, visit [www.daiichisankyo.com](http://www.daiichisankyo.com).

**Daiichi Sankyo, Inc.** ([www.dsus.com](http://www.dsus.com)) headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Co., Ltd.

### **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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Plavix is a registered trademark of Sanofi Aventis Corp.

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.