



FDA Continues to Review Prasugrel New Drug Application

TOKYO and INDIANAPOLIS, Sept 26, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Daiichi Sankyo Company, Limited, (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) confirmed today that the U.S. Food and Drug Administration (FDA) did not complete its review for the prasugrel new drug application (NDA) by the Prescription Drug User Fee Act goal date of September 26, 2008. The proposed indication for prasugrel is for the treatment of patients with acute coronary syndromes (ACS) being managed with an artery-opening procedure known as percutaneous coronary intervention (PCI).

"We remain engaged in collaborative and productive discussions with the FDA regarding the details of our application. This is a very large, complex submission, and it should not be surprising that delays occur," said Jennifer Stotka, M.D., vice president for Global Regulatory Affairs at Lilly. "Daiichi Sankyo and Lilly will not speculate on the timing or what the outcome will be. However, the review is very far along, and we remain optimistic."

"Daiichi Sankyo and Lilly remain confident in the submission package for prasugrel and look forward to bringing this medication to the market for ACS patients who are being managed with PCI," said John Alexander, M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited.

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 syndromes who are managed with PCI. Prasugrel works by inhibiting platelet activation and subsequent aggregation by blocking the P2Y12 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

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 syndromes. 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.

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.

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.

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Editor's Note: Please note this press release will be Daiichi Sankyo and Lilly's only statement at this time.

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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