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FDA Extends Review Period for Daiichi Sankyo, Lilly Investigative Antiplatelet Drug, Prasugrel

Companies confirm the start of TRILOGY ACS clinical trial to study Prasugrel against Clopidogrel in medically managed ACS patients

TOKYO AND INDIANAPOLIS, Ind. (June 23, 2008) – Daiichi Sankyo Company, Limited, (TSE:4568) and Eli Lilly and Company (NYSE: LLY) said that the U.S. Food and Drug Administration (FDA) has extended the review period for the prasugrel new drug application (NDA) based on supplemental information provided during the review period. This three month extension allows the FDA time to complete its review. The prasugrel NDA was granted priority review by the FDA in February 2008. The new FDA action date for prasugrel is 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).

Daiichi Sankyo and Lilly also confirm the start this month, as planned, of the TRILOGY ACS trial, a large Phase III clinical trial to compare the effects of prasugrel against clopidogrel (Plavix®/Iscover®) in medically managed ACS patients.

"We remain confident in our prasugrel submission package," said Jennifer Stotka, M.D., vice president for Global Regulatory Affairs at Lilly. "The TRITON trial encompassed a large amount of data from over 13,000 patients. We will continue to work closely with the FDA throughout the review process and continue discussions to determine if any requirements under the new FDA Amendment Act (FDAAA) legislation will apply."

"The initiation of the TRILOGY ACS trial demonstrates our continued commitment to investigate prasugrel as a potential therapy for ACS patients who are medically managed," said John Alexander, M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited.

About Trilogy ACS

The study, TRILOGY ACS (**T**a**R**geted platelet **I**nhibition to c**L**arify the **O**ptimal strate**G**y to medicall**Y** manage **A**cute **C**oronary **S**yndromes), will include approximately 10,000 patients at more than 800 hospitals in 35 countries.

Daiichi Sankyo and Lilly are conducting the study in conjunction with the Duke Clinical Research Institute (DCRI), the world's largest academic clinical research organization and a part of Duke University Medical Center.

The study is a multi-center, double-blind, randomized, controlled trial to evaluate the safety and efficacy of prasugrel against clopidogrel in reducing the risk of cardiovascular death, heart attack or stroke in ACS patients who are to be medically managed without a planned artery-opening procedure.

Acute coronary syndromes, which comprises heart attacks and unstable angina (chest pain), affects more than 1.4 million people in the United States annually.[1] Despite currently available treatments, 320,000 people experience recurrent heart attacks each year.[2]

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

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

2 American Heart Association. Heart Disease and Stroke Statistics – 2008 Update. Dallas, TX. American Heart Association. (Pg. 12)

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

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.

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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.