



Daiichi Sankyo, Lilly Announce New Prasugrel Head-to-Head Phase III Study Against Clopidogrel

Duke Clinical Research Institute to lead multinational study with investigational compound; will include 10,000 medically managed patients with acute coronary syndrome

TOKYO and INDIANAPOLIS, Nov 04, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- A large Phase III clinical trial is anticipated to begin in the second quarter of 2008 to compare the effects of prasugrel, an investigational oral antiplatelet agent, against clopidogrel (Plavix(R)/Iscover(R)) in medically managed patients with acute coronary syndrome (ACS), a group of common heart conditions that includes unstable angina (chest pain) and heart attacks(1).

The study, TRILOGY ACS (TaRgeted platelet Inhibition to cLarify the Optimal strateGy to medicallY manage Acute Coronary Syndromes), will include approximately 10,000 patients at more than 800 hospitals in 35 countries.

Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY), which are co-developing prasugrel, will conduct 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. Lead study investigator is E. Magnus Ohman, M.D., Professor of Cardiology at Duke University School of Medicine.

About TRILOGY ACS

The study is a multi-center, double-blind, randomized, controlled trial that will include approximately 10,000 patients, with about 800 hospitals in 35 countries participating. TRILOGY ACS will 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 planned revascularization (a procedure to reopen blocked arteries). Currently, more than 50 percent of patients presenting with ACS worldwide are managed without acute intervention.

"TRILOGY ACS, which will be one of the largest of its kind, will be a very important study as it will focus on a group of medically managed patients with ACS who have not been extensively studied in the past," said lead study investigator E. Magnus Ohman, M.D., Professor of Cardiology at Duke University School of Medicine.

When patients present with ACS, their symptoms are secondary to a lack of adequate oxygen delivery to the heart, usually due to a significant narrowing or blockage of one or more of the coronary arteries due to plaque. This plaque has the potential to rupture at any time and cause an arterial clot (thrombus) to form, which can block oxygenated blood from reaching the heart muscle. Antiplatelet medications help to reduce the incidence of this acute thrombus formation.

"The announcement of this study demonstrates our continued confidence in the clinical research surrounding prasugrel," said John Alexander, M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited.

About cardiovascular disease

Cardiovascular disease is the leading cause of death in the U.S. and worldwide, killing 16.7 million people each year(2). Acute heart attacks and unstable angina, called acute coronary syndrome, affect more than 840,000 Americans each year and 800,000 in Europe(3,4). Even with current medical interventions, 300,000 people experience recurrent heart attacks and 500,000 people die from heart attacks annually in the United States(5).

About prasugrel

Daiichi Sankyo Company, Limited (TSE: 4568), and Eli Lilly and Company (NYSE: LLY) are co-developing prasugrel, an investigational oral antiplatelet agent invented by Daiichi Sankyo and its Japanese research partner Ube Industries, Ltd., as a potential treatment, initially for patients with acute coronary syndrome undergoing 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. Building on the strong foundation of ReoPro(R) (abciximab), Lilly is in the process of building a robust cardiovascular pipeline. Lilly has multiple cardiovascular drugs in that pipeline - in every stage from pre-clinical and Phase I to the Phase III trials for prasugrel.

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.

Plavix(R)/Iscover(R) are registered trademarks of Sanofi-Synthelabo Inc.

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- 1 American Heart Association. Heart Disease and Stroke Statistics - 2007 Update. Dallas, TX. American Heart Association. (Pg. 12)
- 2 World Health Organization. The Atlas of Heart Disease and Stroke - Types of cardiovascular disease, 2005.
- 3 American Heart Association. Heart Disease and Stroke Statistics - 2006 Update. Dallas, TX. American Heart Association.
- 4 Bertrand CURE study
- 5 American Heart Association. Heart Disease and Stroke Statistics - 2007 Update. Dallas, TX. American Heart Association. (Pg. 10)

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