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**Refer to:** Joedy Isert  
Eli Lilly and Company  
317-276-5592 (office)  
317-997-8544 (cell)

Jo-ann Straat  
Daiichi Sankyo (USA)  
973-359-2602 (office)

Shigemichi Kondo  
Daiichi Sankyo (Tokyo)  
81-3-6225-1126 (office)

## **Enrollment Completed in Pivotal Phase III Study Comparing Prasugrel to Clopidogrel in Patients with Acute Coronary Syndrome**

TOKYO, Japan and INDIANAPOLIS, Ind. – Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) today announced the completion of patient enrollment in their pivotal Phase III head-to-head clinical study – TRITON TIMI-38 – to evaluate the safety and efficacy of prasugrel compared with clopidogrel (Plavix<sup>®</sup>) in patients with acute coronary syndrome undergoing percutaneous coronary intervention (PCI).

“We are pleased to have completed enrollment in this important Phase III study, which will determine whether the degree of platelet inhibition of prasugrel in earlier studies produces clinical benefits when compared with clopidogrel,” said lead study investigator Elliott Antman, M.D., Director of the Samuel A. Levine Cardiac Unit at Brigham and Women’s Medical Center and senior investigator in the TIMI Study Group.

The TRITON TIMI-38 clinical trial is being conducted in conjunction with the TIMI Study Group at Harvard Medical School and Brigham and Women's Hospital in Boston. The Phase III study is designed to evaluate the safety and efficacy of prasugrel compared with clopidogrel in reducing ischemic events such as heart attacks, stroke and death in patients with acute coronary syndrome undergoing PCI, a procedure to open blockages in heart arteries that includes the use of coronary stents. Patient enrollment began in November 2004 and has reached a total enrollment of 13,614 patients at more than 700 trial sites in 30 countries. In the United States, more than 4,063 patients have been enrolled at 313 trial sites, and in Europe, 2,178 patients have been enrolled at 132 sites.

“We are delighted to see the strong interest from patients and investigators in finding potential new treatment options for acute coronary syndrome,” said Francis Plat, M.D., Daiichi Sankyo Vice President of Cardiovascular Development. “With enrollment completed, we may be a step closer to the development of an innovative therapy that may offer substantial clinical benefits for patients.”

Antiplatelet agents are used both acutely and as maintenance therapy to inhibit platelet activation and subsequent aggregation that occur in diseased arteries and in response to invasive procedures such as PCI. Antiplatelet agents prevent platelets from clumping or sticking together, which can cause formation of blood clots and lead to heart attack or stroke. Recent studies suggest that a relationship may exist between a poor platelet response to antiplatelet agents in individual patients and poor clinical outcomes, which can manifest as major adverse cardiovascular events, including heart attacks.<sup>i,ii,iii</sup>

“Completion of enrollment for the TRITON TIMI-38 trial is a significant milestone in the development program for prasugrel, and demonstrates the shared enthusiasm and dedication of the Daiichi Sankyo and Lilly collaboration,” said J. Anthony Ware, M.D., Ph.D., Lilly Vice President and Global Brand Development Leader for prasugrel.

## **About prasugrel**

Eli Lilly and Company (NYSE: LLY) and Sankyo Company Ltd., a subsidiary of Daiichi Sankyo Company, Limited (TSE: 4568) are co-developing prasugrel, an investigational oral antiplatelet agent, as a potential treatment initially for patients with acute coronary syndrome undergoing PCI. Prasugrel is designed to inhibit platelet activation and 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 cause formation of blood clots and lead to heart attack or stroke.

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

Daiichi Sankyo Company, Limited was established on Sept. 28, 2005, as the joint holding company of two major Japanese pharmaceutical companies – Sankyo Co., Ltd., and Daiichi Pharmaceutical Co., Ltd. Daiichi Sankyo is a global pharmaceutical innovator, continuously generating innovative drugs and services and maximizing its corporate value. Both companies have used their cumulative knowledge and expertise in the field of cardiovascular disease as a foundation for developing an abundant product lineup and R&D pipeline. For further details, please refer to the company Web site at [www.daiichisankyo.co.jp/eng](http://www.daiichisankyo.co.jp/eng).

## **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. Additional information about Lilly is available at [www.lilly.com](http://www.lilly.com).

This press release contains certain forward-looking statements about the potential of the investigational compound prasugrel (CS-747, LY640315) and reflects 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, or that the regulatory approval will be for the indication(s) anticipated by the company. 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. Lilly undertakes no duty to update forward-looking statements. Plavix® is a registered trademark of Sanofi-Synthelabo Inc.

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<sup>i</sup> Barragan, P., Bouvier, J. L., Roquebert, P. O., Macaluso, G., Commeau, P., Comet, B., Lafont, A., Camoin, L., Walter, U., and Eigenthaler, M. Resistance to thienopyridines: clinical detection of coronary stent thrombosis by monitoring of vasodilator-stimulated phosphoprotein phosphorylation. *Catheter Cardiovasc Interv* 2003; 59: 295-302

<sup>ii</sup> Muller, I., Besta, F., Schulz, C., Massberg, S., Schonig, A., and Gawaz, M. Prevalence of clopidogrel non-responders among patients with stable angina pectoris scheduled for elective coronary stent placement. *Thromb Haemost* 2003; 89: 783-787

<sup>iii</sup> Matetzky, S., Shenkman, B., Guetta, V., Shechter, M., Bienart, R., Goldenberg, I., Novikov, I., Pres, H., Savion, N., Varon, D., and Hod, H. Clopidogrel resistance is associated with increased risk of recurrent atherothrombotic events in patients with acute myocardial infarction. *Circulation* 2004; 109: 3171-3175.