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## Daiichi Sankyo, Lilly Submit Marketing Authorization Application for Investigational Oral Antiplatelet Drug, Prasugrel, to European Medicines Agency

The attached is the co-press release with Eli Lilly and Company, which was issued in US and Europe on February 20, 2008.



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# Daiichi Sankyo, Lilly Submit Marketing Authorization Application for Investigational Oral Antiplatelet Drug, Prasugrel, to European Medicines Agency

TOKYO, Japan, and INDIANAPOLIS, Ind. (February 20, 2008) – Daiichi Sankyo Company, Limited (TSE: 4568) and Eli Lilly and Company (NYSE: LLY) announced that they submitted in early February a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) in London seeking approval to market prasugrel within the European Union for the prevention of atherothrombotic events in patients with acute coronary syndrome managed with percutaneous coronary intervention (PCI). A New Drug Application (NDA) for prasugrel was submitted to the U.S. Food and Drug Administration (FDA) on Dec. 26, 2007.

The MAA submission is based upon data from several trials, including the landmark TRITON-TIMI 38 clinical trial, which evaluated the safety and efficacy of prasugrel

compared with clopidogrel in reducing atherothrombotic events (combined endpoint of cardiovascular death, non-fatal heart attack, or non-fatal stroke) in 13,608 patients with acute coronary syndrome managed with PCI. These data were presented at the American Heart Association Scientific Sessions and simultaneously published online in *The New England Journal of Medicine* in November 2007.

"This EMEA submission for prasugrel represents a significant step toward achieving regulatory approval to make this important new treatment option available for patients throughout Europe," said John Alexander, M.D., M.P.H., global head of research and development, Daiichi Sankyo Company, Limited. "Cardiovascular disease remains the leading cause of death worldwide, and we are committed to making important new therapies available to improve patient outcomes."

Cardiovascular disease kills 16.7 million people each year, and acute heart attacks and unstable angina, called acute coronary syndrome, affect more than 800,000 people in Europe each year.<sup>i,ii</sup>

### 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 syndrome 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.

#### P-LLY

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.

<sup>&</sup>lt;sup>i</sup> American Heart Association. Heart Disease and Stroke Statistics - 2006 Update. Dallas, TX. American Heart Association.

<sup>&</sup>lt;sup>ii</sup> Bertrand CURE study