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## Daiichi Sankyo Announces Results of PRASFIT-Elective Study Regarding Use of Prasugrel in Elective Patients with Stable Angina and Chronic Myocardial Infarction Undergoing PCI

Tokyo, Japan (March 14, 2013) — Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced the results from the PRASFIT-Elective study, a double-blind randomized phase 3 trial evaluating efficacy and safety of prasugrel hydrochloride (hereafter, prasugrel) plus aspirin versus clopidogrel sulfate (hereafter, clopidogrel) plus aspirin as a reference in elective patients with stable angina and chronic myocardial infarction undergoing PCI(1). The study began in Japan in 2011 and patients received 24-48 weeks of either prasugrel or clopidogrel. The primary endpoint of the study was to evaluate the efficacy of prasugrel on the composite events of cardiovascular death, non-fatal myocardial infarction or non-fatal ischemic stroke. The follow-up period for this study has been completed and the anticipated data was obtained.

Based on the results of PRASFIT-Elective(2) and PRASFIT-ACS(3) studies, Daiichi Sankyo expects to submit a New Drug Application (NDA) in Japan in the first half of the Japanese fiscal year 2013\* for commercial approval of prasugrel for patients undergoing PCI.

\* The Japanese fiscal year is from April 1 to March 31

In addition to the above-mentioned studies, a Japan domestic phase 3 trial for patients with ischemic cerebrovascular disease is on-going. This trial is expected to complete in the Japanese fiscal year 2014.

The full results of PRASFIT-Elective will be announced at a future medical congress. However, the data from PRASFIT-ACS will be presented in a late breaking session of the 77<sup>th</sup> Annual Scientific Meeting of the Japanese Circulation Society to be held in the Pacifico Yokohama on Saturday, March 16 (14:40-16:10, Late Breaking Clinical Trials 1, Abstract No.1).

## About prasugrel

Prasugrel is an oral antiplatelet agent discovered by Daiichi Sankyo and its Japanese research partner, Ube Industries, Ltd. Prasugrel helps keep blood platelets from clumping together and developing a blockage in an artery. In Japan, Daiichi Sankyo and Ube Industries are co-developing prasugrel and three Phase 3 trials are ongoing. Outside of Japan, based on the co-development by Daiichi Sankyo and Eli Lilly and Company, the European Commission granted marketing authorization for prasugrel for the prevention of atherothrombotic events in patients with ACS undergoing PCI, in combination with aspirin, in 2009. To date prasugrel has been approved in more than 70 countries worldwide.

## **About Elective PCI**

Elective PCI is undertaken in elective patients who have been diagnosed with stable angina, chronic myocardial infarction, or similar conditions, and in whom coronary stenosis and blockage have been confirmed. Heart attacks are a major manifestation of coronary heart disease, which occurs when the arteries become narrowed or clogged by cholesterol and fat deposits.

- (1) PCI: Percutaneous Coronary Intervention
- (2) PRASFIT-Elective Study:

PRASugrel Compared to Clopidogrel For Japanese PatIenTs with Coronary Artery Disease Undergoing Elective PCI

(3) PRASFIT-ACS Study:

PRASugrel Compared to Clopidogrel For Japanese PatIenTs with ACS Undergoing PCI (4)

(4) ACS: Acute Coronary Syndrome