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**Daiichi Sankyo Announces Positive Phase 3 Study Results (PRASFIT-ACS) for Prasugrel  
in Japanese Patients with Acute Coronary Syndrome Undergoing PCI**

**Tokyo, Japan (March 16, 2013)** — Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the results of the PRASFIT-ACS study, a double-blind randomized phase 3 trial comparing efficacy and safety of prasugrel hydrochloride (hereafter, prasugrel) 20 mg loading dose (LD)/3.75 mg maintenance dose (MD) plus aspirin to clopidogrel sulfate (hereafter, clopidogrel) 300 mg LD/75 mg MD plus aspirin in Japanese patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI) were presented at the 77th Annual Scientific Meeting of the Japanese Circulation Society held in the Pacifico Yokohama on Saturday, March 16 (14:40-16:10, Late Breaking Clinical Trials 1, Abstract No.1).

The incidence of the composite primary endpoint (cardiovascular (CV) death, non-fatal myocardial infarction, ischemic stroke) at 24 weeks in prasugrel patients was 9.4 percent, while 11.8 percent in clopidogrel patients (RR\*=23 percent). The incidence of non-CABG (coronary artery bypass graft) related TIMI-major bleeding occurred in 1.9 percent of prasugrel patients versus 2.2 percent of clopidogrel patients. The incidence of TIMI-major, minor or clinically relevant bleeding was similar in the both groups (9.6 percent of prasugrel patients versus 9.6 percent of clopidogrel patients).

RR\*: risk reduction

Shigeru Saito, M.D, Vice Director, Director of Cardiology and Catheterization Laboratories at Shonan Kamakura General Hospital said, “The PRASFIT-ACS trial was the largest phase 3 comparative clinical trial conducted in ACS-PCI patients in Japan. In a Japanese phase 2 clinical study prasugrel 20 mg LD/ 3.75 mg MD provided consistent and potent platelet inhibition. <sup>1</sup> Based on this result prasugrel 20 mg LD/ 3.75 mg MD was the selected dose for conducting PRASFIT-ACS clinical study. As a result, the fact that the incidence rate of cardiovascular events in prasugrel patients was 9.4 percent, while 11.8 percent in

clopidogrel patients and its risk reduction was 23 percent, and the fact that no difference in bleeding tendency between both groups are very meaningful for patients undergoing PCI from a clinical standpoint in Japan. Now that the PRASFIT-ACS has shown a consistent trend in terms of efficacy results to the TRITON-TIMI38 study and at the dose studied in PRASFIT-ACS, similar tolerability was shown compared to clopidogrel for Japanese ACS-PCI patients. I expect prasugrel to become a standard therapeutic drug for ACS-PCI treatment in Japan.”

[Note: The indicated dose for prasugrel in the outside of Japan is 60mg LD and 10mg MD]

Glenn Gormley, M.D., Ph.D., Global Head of Research and Development and Senior Executive Officer, Daiichi Sankyo Co. LTD and President of Daiichi Sankyo Pharma Development said “We are pleased that the results of "PRASFIT-ACS" are available and that prasugrel demonstrated a risk reduction tendency in the composite endpoint of CV death, non-fatal MI and non-fatal ischemic stroke at the 24-week follow-up period in Japanese ACS-PCI patients, without an increase of clinically relevant bleeding compared to clopidogrel group. We would like to thank the leadership of the Japanese investigators in completing this study. We look forward to bringing this important therapy option to ACS-PCI patients in Japan.”

In Japan, Daiichi Sankyo also completed a PRASFIT-Elective phase 3 clinical study that evaluated the efficacy and safety of prasugrel in elective patients with stable angina and chronic myocardial infarction undergoing PCI.

Based on the results of PRASFIT-ACS study and PRASFIT-Elective study, 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 abovementioned studies, a Japanese 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.

### **About PRASFIT-ACS**

PRASFIT-ACS study was a phase 3, multi-center, randomized, double blind, parallel group clinical trial comparing the efficacy and safety of prasugrel plus aspirin versus clopidogrel plus aspirin in patients with acute coronary syndrome undergoing PCI in Japan. The study enrolled 1,363 patients and patients received 24-48 weeks of either prasugrel (N=685) or clopidogrel (N=678).

Patients were randomly assigned to one of two treatment groups and given a loading dose of either prasugrel 20 mg or the approved loading dose of clopidogrel 300 mg upon the PCI procedure, followed by a daily maintenance dose of either prasugrel 3.75 mg or clopidogrel 75 mg.

The primary endpoint of the study was to compare the effects of prasugrel to clopidogrel on the composite incidence of cardiovascular death, non-fatal myocardial infarction and non-fatal ischemic stroke for during the 24 week follow-up period. The safety endpoint of the study included non-CABG TIMI major, TIMI minor or clinically relevant bleeding.

### **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 and the FDA 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 Acute Coronary Syndromes(ACS)**

Acute coronary syndrome includes heart attacks and unstable angina (chest pain). Heart attack is a major manifestation of coronary heart disease, which occurs when the arteries become narrowed or clogged by cholesterol and fat deposits. In some cases the plaque can rupture, resulting in a blood clot which may partially or totally block the blood supply to portions of the heart, resulting in ACS.<sup>2</sup>

Among total deaths in 2011 according to cause of death, heart disease (not including hypertension) was second after malignant growths (cancer), accounting for 194,926 deaths or 15.6% of the total. Moreover, within this number, 43,265 deaths from acute myocardial infarction, or 22.2% were recorded, while deaths from “other ischemic heart disease” totaled 34,576, or 17.7%.<sup>3</sup>

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<sup>1</sup> Takaaki Isshiki et al., Cardiovascular Intervention and Therapeutics, CVIT 2011

<sup>2</sup> WebMD Medical Reference in Collaboration with the Cleveland Clinic. Heart Disease: Coronary Artery Disease. Available at: [www.webmd.com/heart-disease/guide/heart-disease-coronary-artery-disease](http://www.webmd.com/heart-disease/guide/heart-disease-coronary-artery-disease). Accessed May 2012.

<sup>3</sup> <http://www.mhlw.go.jp/toukei/saikin/hw/jinkou/kakutei11/>