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# Subgroup Analysis of PRASFIT-ACS Study Evaluated Impact of Platelet Reactivity on Prevention of Ischemic Events in Perioperative Period of PCI

**Tokyo, Japan (March 24, 2014)** — Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the results of a subgroup analysis of the PRASFIT-ACS study were presented at the 78th Annual Scientific Meeting of the Japanese Circulation Society held in the Tokyo International Forum on March 22.

In the full analysis set for the PRASFIT-ACS study (N=1,363), the incidence of MACE (major adverse cardiovascular events) within 3 days after percutaneous coronary intervention (PCI) in the prasugrel group was 5.6% versus 8.3% for the clopidogrel group showing a significant reduction in the incidence of MACE in the prasugrel group (RR*=37%; hazard ratio: 0.63; 95% Confidence Interval: [CI] 0.41-0.95, p=0.026).
RR*: risk reduction

The subgroup analysis was conducted in patients (N=660) whose P2Y12 reaction units (PRU), an index of platelet aggregation activity at 5-12 hours after loading dose (LD) were measured. The results of the subgroup analysis showed the correlation between PRU at 5-12 hours after LD and the incidence of MACE within three days after PCI suggesting that in order to prevent ischemic events in the perioperative period of PCI, it is necessary to reduce rapidly platelet aggregation activity.

**About PRASFIT-ACS**

PRASFIT-ACS (**PRAS**ugrel Compared to Clopidogrel **F**or Japanese Pat**I**en**T**s with **ACS** Undergoing PCI) 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 incidence of the composite primary endpoint (cardiovascular (CV) death, non-fatal myocardial infarction, ischemic stroke) at 24 weeks in prasugrel patients was 9.4%, while 11.8% in clopidogrel patients (RR=23%, HR 0.77, 95% CI 0.56-1.07, P=0.12）. The incidence of non-CABG (coronary artery bypass graft) related TIMI-major bleeding occurred in 1.9% of prasugrel patients versus 2.2 % of clopidogrel patients. The incidence of TIMI-major, minor or clinically relevant bleeding was similar in the both groups (9.6 % of prasugrel patients versus 9.6% of clopidogrel patients).

The results of PRASFIT-ACS study were presented at the 77th Annual Scientific Meeting of the Japanese Circulation Society held in the Pacifico Yokohama in March 16, 2013.

**About Subgroup Analysis of PRASFIT-ACS**

In this subgroup analysis, the relationship between PRU at 5-12 hours after LD and the incidence of MACE within three days after PCI was evaluated. By evaluating the correlation between PRU and MACE, the cutoff value (PRU=262) to predict the prevention of MACE was calculated. The incidence of MACE in the group whose PRU was less than the cutoff value was 5.2% versus 10.8% for the group whose PRU was more than the cutoff value (odds ratio: 0.50; 95% CI: 0.25-0.99; $p<0.001$). The portion of the patients with less than the cutoff value in the prasugrel group was 79.9% versus 30.4% in the clopidogrel group ($p<0.001$).

**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.

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.[1]

**References**

1 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 Accessed June 2013.