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**Daiichi Sankyo Announces Phase 3 Study Results (PRASFIT-Elective Study) for
the Antiplatelet Agent Prasugrel in Japan**

Tokyo, Japan (July 12, 2013) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that the results of a phase 3 clinical study (PRASFIT-Elective study)¹ for the antiplatelet agent prasugrel hydrochloride (hereafter, prasugrel) in Japanese patients with coronary artery disease (stable angina or history of previous myocardial infarction, or myocardial infarction) undergoing elective PCI² were presented at the 22nd Annual Meeting of the Japanese Association of Cardiovascular Intervention and Therapeutics; CVIT 2013.

The incidence of the composite primary endpoint (cardiovascular death, non-fatal myocardial infarction, ischemic stroke) was 4.1 percent in the prasugrel group versus 6.7 percent in the clopidogrel sulfate (hereafter, clopidogrel) group. The incidence of non-CABG (coronary artery bypass graft) TIMI major, minor or clinically relevant bleeding was 5.4 percent in the prasugrel group versus 6.2 percent in the clopidogrel group. The incidence of non-CABG TIMI major bleeding in the prasugrel group was 0.0 percent, while in the clopidogrel group, it was 2.2 percent. The efficacy and safety results of this study are similar to those of the PRASFIT-ACS study³.

Daiichi Sankyo submitted a New Drug Application to the Ministry of Health, Labour and Welfare in Japan⁴ for the treatment of patients with ischemic heart disease undergoing PCI based on the results of the PRASFIT-ACS and PRASFIT-Elective studies on June 18, 2013.

A Japanese phase 3 trial of prasugrel for patients with ischemic cerebrovascular disease is on-going. This trial is expected to be completed in fiscal year 2014*.

*: From April 1, 2014, to March 31, 2015.

About PRASFIT-Elective study

PRASFIT-Elective is a phase 3, multi-center, randomized, double-blind, double-dummy, parallel group clinical study in Japan to evaluate the efficacy and safety of prasugrel plus aspirin using clopidogrel plus aspirin (as a reference) in patients with stable angina and chronic myocardial infarction undergoing elective PCI. The primary endpoint of the study was the composite incidence of cardiovascular death, non-fatal myocardial infarction and non-fatal ischemic stroke during the 24 week follow-up period. The safety endpoints included non-CABG TIMI major, minor or clinically relevant bleeding. A total of 742 patients were enrolled and received 24 to 48 weeks of either prasugrel or clopidogrel. In current medical practice, patients undergoing elective PCI either start administration with a loading dose (LD) or a maintenance dose (MD), which is decided at the medical institution for each patient. Patients were randomly assigned to the prasugrel group (N=370) or the clopidogrel group (N=372) (LD group: N=269 for prasugrel vs. N=266 for clopidogrel; MD group: N=101 for prasugrel vs. N=106 for clopidogrel). Patients started with the LD were given a LD of either prasugrel 20 mg or clopidogrel 300 mg followed by a daily MD of either prasugrel 3.75 mg or clopidogrel 75 mg. Patients started with the MD were given a MD of prasugrel 3.75 mg or clopidogrel 75 mg for at least 14 days before undergoing PCI.

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. 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 Elective PCI

Elective PCI is undertaken in patients who have been diagnosed with coronary artery disease (stable angina or history of previous myocardial infarction, or myocardial infarction), and in whom coronary stenosis and blockage have been confirmed.

About Acute Coronary Syndrome

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 ACS⁵.

References

- 1 PRASFIT-Elective Study:
PRASugrel For Japanese PatIenTs with Coronary Artery Disease Undergoing Elective PCI
- 2 PCI: Percutaneous Coronary Intervention
- 3 PRASFIT-ACS Study:
PRASugrel Compared to Clopidogrel For Japanese PatIenTs with ACS Undergoing PCI
The results of this study were announced at the 77th Annual Scientific Meeting of the Japanese Circulation Society held in the Pacifico Yokohama on March 16, 2013 in a late breaking clinical trial session (14:40-16:10, Late Breaking Clinical Trials 1, Abstract No.1) and a subsequent press release.
http://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/005126.html
- 4 Refer to the June 18, 2013 news release entitled, “Daiichi Sankyo Submits a New Drug Application in Japan for the Antiplatelet Agent Prasugrel.”
http://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/005988.html
- 5 ACS: Acute Coronary Syndrome