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Daiichi Sankyo Announces PRASFIT-ACS Results Regarding Prasugrel in Acute Coronary Syndrome Patients Undergoing PCI

-PRASFIT-ACS study has been conducted in Japan-

Tokyo, Japan (September 21, 2012) — Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced data from the PRASFIT-ACS study, a double-blind randomized phase 3 trial comparing efficacy and safety of prasugrel plus aspirin to clopidogrel plus aspirin in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI). The study began in Japan in 2010 and patients received 24-48 weeks of either prasugrel or clopidogrel. The primary endpoint of the study was to compare the efficacy of prasugrel versus clopidogrel 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.

In Japan, Daiichi Sankyo is also currently conducting a phase 3 study on elective PCI patients. The study is expected to complete in fiscal year 2012.

Based on the results of these two studies, Daiichi Sankyo expects to submit a New Drug Application (NDA) in fiscal year 2013 in Japan for commercial approval of prasugrel for patients undergoing PCI.

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

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 65 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

¹ WebMD Medical Reference in Collaboration with the Cleveland Clinic. Heart Disease: Coronary Artery Disease. Available at: <u>www.webmd.com/heart-disease/guide/heart-disease-coronary-artery-disease</u>. Accessed May 2012.