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Daiichi announces trial results for Prasugrel

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Singapore: Daiichi Sankyo has announced data from the PRASFIT-ACS study, a double-blind randomized phase III 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, nonfatal 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 III 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 said it 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 III trial for patients with ischemic cerebrovascular disease is also on-going. The trial is expected to complete in fiscal year 2014.