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Daiichi gets positive results in prasugrel trial

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Singapore: Japanese company Daiichi Sankyo has received positive results for a double-blind randomized phase III trial comparing efficacy and safety of prasugrel hydrochloride 20 mg loading dose (LD)/3.75 mg maintenance dose (MD) plus aspirin to clopidogrel sulfate 300 mg LD/75 mg MD plus aspirin in Japanese patients with acute coronary syndrome undergoing percutaneous coronary intervention (PCI).

The incidence of the composite primary endpoint (cardiovascular death, non-fatal myocardial infarction, ischemic stroke) at 24 weeks in prasugrel patients was 9.4 percent, while 11.8 percent in clopidogrel patients. The incidence of non-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).

Dr Shigeru Saito, vice director, director of Cardiology and Catheterization Laboratories at Shonan Kamakura General Hospital, said, "The PRASFIT-ACS trial was the largest phase III comparative clinical trial conducted in ACS-PCI patients in Japan. In a Japanese phase II clinical study, prasugrel 20 mg LD/ 3.75 mg MD provided consistent and potent platelet inhibition."

"I expect prasugrel to become a standard therapeutic drug for ACS-PCI treatment in Japan," he added.

Dr Glenn Gormley, global head of Research and Development and senior executive officer, Daiichi Sankyo, 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 III 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 the two studies, Daiichi Sankyo expects to submit a new drug application in Japan in the first half of the Japanese fiscal year 2013 for commercial approval of prasugrel for patients undergoing PCI.

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