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Daiichi Sankyo files NDA for Prasugrel in Japan

19 June 2013 | News | By BioSpectrum Bureau

Singapore: Japanese drug major Daiichi Sankyo submitted a New Drug Application to the Ministry of Health, Labor and Welfare in Japan for the antiplatelet agent Prasugrel for the treatment of patients with ischemic heart disease undergoing percutaneous coronary intervention (PCI). Analysts at Credit Suisse have a net present value for Prasugrel of $0.82 (78.19 Yen) per share (4% of total) for Daiichi Sankyo.

The application is based on the results of a Phase III trial in Japanese patients with acute coronary syndrome (ACS) undergoing PCI (PRASFIT-ACS) and a Phase III study in Japanese patients with coronary artery disease (stable angina or history of previous myocardial infarction, or myocardial infarction) undergoing elective PCI (PRASFIT-Elective). A Japanese domestic Phase III trial of Prasugrel for patients with ischemic cerebrovascular disease is ongoing. This trial is expected to be completed in fiscal year 2014.

Prasugrel is an oral antiplatelet agent discovered by Daiichi Sankyo and its Japanese research partner, Ube Industries. In Japan, Daiichi Sankyo and Ube Industries are co-developing Prasugrel.

Outside of Japan, based on the co-development by Daiichi Sankyo and US drug major Eli Lilly, which markets the drug under the trade name Effient, the European Commission and the US Food and Drug Administration 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.