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Daiichi Sankyo Announces Phase 3 Clinical Trial (PRASTRO-I Study, PRASTRO-II Study) Results for Prasugrel Antiplatelet Agent for Patients with Ischemic Cerebrovascular Disease

Tokyo, Japan (October 21, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo), today announced the results of Phase 3 clinical trials in Japan of the antiplatelet agent prasugrel hydrochloride (hereafter, prasugrel) for ischemic cerebrovascular disease patients.

The PRASTRO-I study was conducted in 3,747 ischemic cerebrovascular disease patients, excluding cardiogenic cerebral embolisms, aged 75 years and under and weighing more than 50 kg to verify non-inferiority in efficacy of prasugrel administered once daily in a 3.75 mg dose compared to the once daily administration of a 75 mg dose of clopidogrel. In this study, the primary endpoint of reduction of cerebro-cardiovascular events (ischemic stroke, myocardial infarction or other vascular death) was not achieved. Additionally, no new concerns for the safety of prasugrel were observed.

The PRASTRO-II study was conducted in 654 ischemic cerebrovascular disease patients, excluding cardiogenic cerebral embolisms, aged 75 years or older and/or weighing 50 kg or less to evaluate safety (the incidence of clinically relevant bleeding) of prasugrel administered once daily in 3.75 mg or 2.5 mg doses compared to the once daily administration of a 50 mg dose of clopidogrel. In this study, the intended purpose of study was achieved in both the primary endpoint (frequency of clinically important bleeding events) and the secondary endpoint (frequency of cerebro-cardiovascular events).

Detailed results for both studies are expected to be published at future academic conferences.

About prasugrel

Prasugrel is an oral antiplatelet agent discovered by Daiichi Sankyo and its Japanese research partner Ube Industries, Ltd., originating from Japan. Clinical trials in Japan and other countries have confirmed prasugrel to be an effective and stable antiplatelet effect for duration of the treatment time, and reducing risk of cardiovascular events in ischemic heart disease patients undergoing percutaneous coronary intervention (PCI).

In Japan, prasugrel has been approved as a treatment for ischemic heart disease patients as of March 2014. Its dosage for adult patients is set to one 20 mg dose orally on the first day and one daily 3.75 mg thereafter.

Outside of Japan, prasugrel has been co-developed by Daiichi Sankyo and Eli Lilly and Company and granted marketing authorization in Europe and the United States in 2009 for prevention of atherothrombotic events in patients with acute coronary syndrome undergoing PCI. To date, prasugrel has been approved in more than 80 countries worldwide.

About Ischemic Cerebrovascular Disease

Ischemic cerebrovascular disease, also known as cerebral infarction, occurs when blood vessels supplying blood (blood flow) to the brain are blocked, leading to neurologic deficit. A number of the causes that lead to the development of cerebral infarction are known, one of these being brain blood vessel thrombosis caused by blood clots in the blood vessel walls, which is also a major cause of blood vessel obstruction.

In 2015, cerebrovascular disease accounted for 111,973 (8.7%) of all cause-specific deaths, making it the fourth leading cause of death in Japan. Of these deaths, excluding those caused by hemorrhagic stroke or other cerebrovascular disease, cerebral infarction accounted for 64,523 deaths or 57.6% of all brain vascular disease patients^{*1}.

^{*1} Demographic statistics, 2015 in Japan (in Japanese only)
http://www.mhlw.go.jp/toukei/saikin/hw/jinkou/kakutei15/index.html