Press Release

Company name: DAIICHII SANKYO COMPANY, LIMITED
Representative: Sunao Manabe, Representative Director, President and CEO
(Code no.: 4568, First Section, Tokyo Stock Exchange)
Release address inquiries to Junichi Onuma,
Vice President, Corporate Communications Department
Telephone: +81-3-6225-1126
https://www.daiichisankyo.com

Daiichi Sankyo Submits Supplemental Application in Japan for Approval of Partial Changes Related to Additional Indication for the Antiplatelet Agent, Prasugrel Hydrochloride

Tokyo, Japan (December 15, 2020) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced today that a supplemental application for the antiplatelet agent, prasugrel hydrochloride (hereafter, prasugrel), was filed in Japan to expand the indication for prevention of recurrence of ischemic stroke as a partial change in items of the pharmaceutical manufacturing and marketing approval for prasugrel.

This application is based on the results of a phase 3 study in thrombotic stroke patients in Japan (PRASTRO-III study), as well as other phase 3 studies in Japan targeting patients with ischemic cerebrovascular disease (PRASTRO-I and PRASTRO-II studies).

Daiichi Sankyo is committed to providing new treatment options for ischemic stroke patients.

About ischemic cerebrovascular disease and thrombotic stroke

Ischemic cerebrovascular disease, or ischemic stroke, occurs when blood flow in the brain are somehow blocked, causing damage to brain tissue.

There are several types of ischemic cerebrovascular disease (ischemic stroke). Thrombotic stroke is one of them, and is a type of stroke that occurs due to occlusion of cerebral blood vessels by platelet thrombi, which build up mainly as a result of atherosclerosis.

The PRASTRO-I study

A study conducted in 3,747 patients with ischemic cerebrovascular disease (excluding those with cardiogenic cerebral embolisms) aged under 75, and with body weight over 50 kg, to verify non-inferiority in efficacy of prasugrel compared to clopidogrel.

The PRASTRO-II study

A study conducted in 654 patients with ischemic cerebrovascular disease (excluding those with cardiogenic cerebral embolisms) aged 75 and over, or with body weight under 50 kg, to evaluate safety of prasugrel compared to clopidogrel.

The PRASTRO-III study

A double-blind comparative study conducted in 234 thrombotic stroke patients with one or more risk factors for the recurrence of stroke to examine efficacy and safety between prasugrel and clopidogrel treatment groups.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: https://www.daiichisankyo.com/