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Daiichi-Sankyo

Press Release

Daiichi Sankyo Obtains Supplemental New Drug Application Approval Submitted for Additional Indication and Dosage and Administration of Antiplatelet Agent "Efient® 3.75 mg Tablets" and "Efient® 2.5 mg Tablets" in Japan

Tokyo, Japan - (December 24, 2021) — Daiichi Sankyo Company, Limited (hereinafter, Daiichi Sankyo) today announced that it has obtained a supplemental new drug application approval for additional indication and dosage and administration of the antiplatelet agents "Efient® 3.75 mg Tablets" and "Efient® 2.5 mg Tablets" (generic name prasugrel hydrochloride, hereinafter "Efient® Tablets") in Japan. This approval authorizes Efient® Tablets to be used for "Prevention of recurrence of ischemic cerebrovascular disease following the former appearance of ischemic cerebrovascular disease (associated with large-artery atherosclerosis or small-vessel occlusion) (restricted to cases with a high risk of ischemic stroke)."

In December 2020, Daiichi Sankyo submitted an application for the partial change approval in approved items for drug marketing of Efient® Tablets based on results from a phase 3 study in thrombotic stroke patients in Japan (PRASTRO-III study) and other phase 3 studies in Japan targeting patients with ischemic cerebrovascular disease (PRASTRO-I and PRASTRO-II studies).

By delivering a new option for the treatment of ischemic cerebrovascular diseases, Daiichi Sankyo hopes to contribute to the healthcare of patients.

Brief Description of Efient® Tablets

Product Name	Efient® 2.5 mg Tablets Efient® 3.75 mg Tablets Efient® 5 mg Tablets Efient® 20 mg OD Tablets
Generic Name	Prasugrel hydrochloride
Indications (underline: additional indication)	Efient® 2.5 mg Tablets Efient® 3.75 mg Tablets Efient® 5 mg Tablets Efient® 20 mg OD Tablets

	• The following ischemic heart diseases that require percutaneous coronary intervention (PCI): Acute coronary syndromes (ACS; unstable angina [UA], non-ST-segment elevation myocardial infarction [NSTEMI], or ST-segment elevation myocardial infarction [STEMI]), Stable angina, old myocardial infarction Efient® 2.5 mg Tablets Efient® 3.75 mg Tablets • <u>Prevention of recurrence of ischemic cerebrovascular disease following the former appearance of ischemic cerebrovascular disease (associated with large-artery atherosclerosis or small-vessel occlusion) (restricted to cases with a high risk of ischemic stroke)</u>
Dosage and Administration (underline: additional dosage and administration)	<Ischemic heart diseases that require percutaneous coronary intervention (PCI)> Usually for adults, prasugrel should be initiated with a single 20 mg oral dose and then continued at a 3.75 mg once daily oral dose as a maintenance dose <<u>Prevention of recurrence of ischemic cerebrovascular disease following the former appearance of ischemic cerebrovascular disease (associated with large-artery atherosclerosis or small-vessel occlusion)</u>> <u>Usually for adults, prasugrel should be administered at a 3.75 mg once daily oral dose</u>
Date of Partial Change Approval	December 24, 2021
Manufacturing and Marketing	Daiichi Sankyo Company, Limited

<u>PRASTRO-I study</u>

This study verified the non-inferiority in the efficacy of prasugrel hydrochloride to clopidogrel in 3,747 patients with ischemic cerebrovascular disease (excluding those with cardioembolic stroke) younger than 75 years and weighing more than 50 kg.

<u>PRASTRO-II study</u>

This study evaluated the safety of prasugrel hydrochloride in 654 patients with ischemic cerebrovascular disease (excluding those with cardioembolic stroke) aged 75 years or older and weighing 50 kg or less using clopidogrel as the control.

PRASTRO-III study

This study compared the efficacy and safety of prasugrel hydrochloride and clopidogrel in 234 patients with thrombotic stroke and at least one risk factor for the recurrence of ischemic stroke.

About Daiichi Sankyo

Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical need. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." For more information, please visit www.daiichisankyo.com.

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