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For Immediate Release

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**Daiichi Sankyo Receives Approval in Japan for Manufacturing and Marketing of the Antiplatelet Agent Efient<sup>®</sup> 3.75mg/5mg Tablets**

**Tokyo, Japan (March 24, 2014)** – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced that it has received approval from the Ministry of Health, Labour and Welfare in Japan for the antiplatelet agent Efient<sup>®</sup> 3.75mg/5mg Tablets (JAN: Prasugrel Hydrochloride) for the treatment of patients with ischemic heart disease undergoing PCI<sup>1</sup>.

Efient<sup>®</sup> is an oral antiplatelet agent discovered by Daiichi Sankyo and its Japanese research partner, Ube Industries, Ltd. Efient<sup>®</sup> reduces the incidence of ischemic events in perioperative period of PCI by rapidly reducing platelet aggregation activity.

Daiichi Sankyo has submitted the new drug application in Japan based on the results of a phase 3 trial in Japanese patients with ACS<sup>2</sup> undergoing PCI (PRASFIT-ACS<sup>3</sup>) and a phase 3 trial in Japanese patients with coronary artery disease (stable angina or history of previous myocardial infarction, or myocardial infarction) undergoing elective PCI (PRASFIT-Selective<sup>4</sup>).

With approval of the Efient<sup>®</sup> treatment option in Japan, Daiichi Sankyo aims to benefit patients and healthcare professionals by providing a new approach to therapy for ischemic heart disease.

Outside of Japan, based on the co-development by Daiichi Sankyo and Eli Lilly and Company, the European Commission and the FDA granted marketing authorization for Efient<sup>®</sup>/Effient<sup>®</sup> 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.

### Product overview

Name	Efient® 3.75mg/5mg Tablets
Generic name (JAN)	Prasugrel Hydrochloride
Indication	Prasugrel is indicated for the following ischemic cardiac diseases, which require percutaneous coronary intervention (PCI): <ul style="list-style-type: none"><li>• Acute coronary syndromes (Unstable angina, Non ST-segment elevation myocardial infarction or ST-segment elevation myocardial infarction)</li><li>• Stable angina, Old myocardial infarction</li></ul>
Dosage and administration	Prasugrel should be initiated orally with a single 20-mg loading dose and then continued at a 3.75-mg once daily dose for adults.
Approval date	March 24, 2014

#### About Acute Coronary Syndrome

Acute coronary syndrome includes heart attacks and unstable angina (chest pain). Heart attack is a major manifestation of coronary heart disease, which occurs when the arteries become narrowed or clogged by cholesterol and fat deposits. In some cases the plaque can rupture, resulting in a blood clot which may partially or totally block the blood supply to portions of the heart, resulting in ACS<sup>5</sup>.

#### About Elective PCI

Elective PCI is undertaken in patients who have been diagnosed with coronary artery disease (stable angina or history of previous myocardial infarction, or myocardial infarction), and in whom coronary stenosis and blockage have been confirmed.

#### References

1 PCI: Percutaneous Coronary Intervention

2 ACS: Acute Coronary Syndrome

3 PRASFIT-ACS Study:

##### **PRASugrel Compared to Clopidogrel For Japanese PatIenTs with ACS Undergoing PCI**

The results of this study were announced at the 77th Annual Scientific Meeting of the Japanese Circulation Society held in the Pacifico Yokohama on March 16, 2013 in a late breaking clinical trial session (14:40-16:10, Late Breaking Clinical Trials 1, Abstract No.1) and a subsequent press release.

[http://www.daiichisankyo.com/media\\_investors/media\\_relations/press\\_releases/detail/005126.html](http://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/005126.html)

4 PRASFIT-Elective Study:

##### **PRASugrel For Japanese PatIenTs with Coronary Artery Disease Undergoing Elective PCI**

The results of this study will be announced at the 22nd Annual Meeting of the Japanese Association of Cardiovascular Intervention and Therapeutics; CVIT 2013 Congress (Thursday July 11, 4:30-6:00 p.m. Late Breaking Clinical Study, No. LB1-4)

[http://www.daiichisankyo.com/media\\_investors/media\\_relations/press\\_releases/detail/006002.html](http://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006002.html)

5 WebMD Medical Reference in Collaboration with the Cleveland Clinic. Heart Disease: Coronary Artery Disease. Available at: [www.webmd.com/heart-disease/guide/heart-disease-coronary-artery-disease](http://www.webmd.com/heart-disease/guide/heart-disease-coronary-artery-disease)  
Accessed June 2013.