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For Immediate Release

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### **Daiichi Sankyo Submits a New Drug Application in Japan for the Antiplatelet Agent Prasugrel**

**Tokyo, Japan (June 18, 2013)** – Daiichi Sankyo Co., Ltd. (hereafter, Daiichi Sankyo) today announced that it has submitted a New Drug Application to the Ministry of Health, Labour and Welfare in Japan for the antiplatelet agent prasugrel hydrochloride (hereafter, prasugrel) for the treatment of patients with ischemic heart disease undergoing PCI <sup>1</sup>.

The application is 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 prasugrel treatment option in Japan, Daiichi Sankyo aims to benefit patients and healthcare professionals by providing a new approach to therapy for ischemic heart disease.

A Japanese domestic phase 3 trial of prasugrel for patients with ischemic cerebrovascular disease is on-going. This trial is expected to be completed in fiscal year 2014\*.

\*: From April 1, 2014, to March 31, 2015.

#### **About prasugrel**

Prasugrel is an oral antiplatelet agent discovered by Daiichi Sankyo and its Japanese research partner, Ube Industries, Ltd. Prasugrel helps keep blood platelets from clumping together and developing a blockage in an artery. In Japan, Daiichi Sankyo and Ube Industries are co-developing prasugrel. 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 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.

### **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)

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.