

## **Discontinuation of Clinical Studies of CS-505 (Pactimibe; Sankyo's ACAT Inhibitor)**

(Tokyo, JAPAN October 26, 2005) – DAIICHI SANKYO COMPANY, LIMITED announced today that Sankyo Company, Limited has decided to discontinue all ongoing clinical studies of pactimibe CS-505, Acyl-coenzyme A:cholesterol acyltransferase (ACAT) inhibitor.

This decision was made because pactimibe did not meet the primary endpoint in the coronary intravascular ultrasound study (Study 505-202, ACTIVATE). Analysis of the secondary endpoints showed a lower effect of pactimibe on atherosclerosis than standard of care alone and no beneficial effect on the frequency of cardiovascular events. As a result, all ongoing clinical studies with pactimibe will be discontinued. Additional details will be provided at the 2005 American Heart Association's Scientific Sessions on November 15<sup>th</sup>.

### **About the ACTIVATE Study**

The **ACTIVATE** (**ACAT** **I**ntra**V**ascular **A**therosclerosis **T**reatment **E**valuation) study was a randomized, double-blind, placebo-controlled trial evaluating the safety and efficacy of pactimibe in reducing the progression of coronary atherosclerosis in subjects with established coronary artery disease. The study involved 534 patients with documented atherosclerotic cardiovascular disease (ASCVD). The patients were randomized to receive either pactimibe 100 mg or placebo once daily in addition to standard care, which included statin therapy. The primary endpoint of the trial was the change from baseline in percent atheroma volume, as measured by coronary intravascular ultrasound (IVUS), after 18 months. IVUS methodology, in which a catheter containing a tiny ultrasound probe is inserted into a coronary artery to directly image and measure the size of the atherosclerotic plaques, is considered more sensitive than traditional coronary angiography (CAG) in measuring the progression of coronary atherosclerosis.

## **About Pactimibe (CS-505)**

Pactimibe is a novel investigational agent of a new class of cardiovascular drugs intended to provide potent inhibition of acyl-CoA:cholesterol O-acyltransferase (ACAT), the enzyme responsible for esterification of cholesterol. ACAT promotes accumulation of esterified cholesterol in vascular macrophages, thereby contributing to foam cell formation, a characteristic of early atherosclerosis. Pactimibe was under development to inhibit this ACAT activity, affecting the way cholesterol is stored in the body and preventing buildup at the boundary between the artery wall and cholesterol plaque. In previous animal experiments, pactimibe reduced the progression of atherosclerosis.

## **About Atherosclerosis**

Atherosclerosis is the process by which fat deposits build up as plaque inside arteries. If atherosclerosis progresses far enough, blood vessels will become clogged, resulting in a heart attack.

## **About DAIICHI SANKYO COMPANY, LIMITED. and Sankyo Company, Limited**

DAIICHI SANKYO COMPANY, LIMITED was established on September 28, 2005 as the joint holding company of two major Japanese pharmaceutical companies – Sankyo Company, Limited and Daiichi Pharmaceutical Co., Ltd. DAIICHI SANKYO aims to become a Global Pharma Innovator, continuously generating innovative drugs and services and maximizing its corporate value. Sankyo and Daiichi Pharmaceutical have a broad range of major drug products on the Japanese market, including the antihypertensive Olmetec® (olmesartan medoxomil) and the synthetic antibacterial agent Cravit® (levofloxacin) and are strongly promoting drug information provision activities. Both companies specialize in the field of cardiovascular disease and have used their cumulative knowledge and expertise as a foundation for developing an abundant product lineup and R&D pipeline.

For further details, please refer to the company Web site, at [www.daiichisankyo.co.jp](http://www.daiichisankyo.co.jp)

Sankyo Company, Limited of Tokyo, one of Japan's largest pharmaceutical companies and wholly owned company of DAIICHI SANKYO COMPANY, LIMITED has a long history of discovering new classes of drugs, including the statin class of lipid-lowering drugs. Beginning with its discovery of the first statin, mevastatin, and the co-discovery of lovastatin, the first statin to be marketed, Sankyo has been a pioneer in the cardiovascular disease arena. Additionally, Sankyo discovered, developed, manufactures and markets pravastatin sodium and olmesartan medoximil, an angiotensin II receptor blocker (ARB). Sankyo also developed and launched the first glitazone, which revolutionized long-term control of type 2 diabetes, and has a number of other potentially promising compounds in the diabetes arena. Sankyo's early stage pipeline focuses on oral therapies to satisfy key unmet needs in six major fields -- cardiovascular disease, metabolic disease, respiratory and immune disease, bone and joint disease, infectious disease, and oncology. For further information about Sankyo and its products, log on to <http://www.sankyo.co.jp/english/>

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