

For Immediate Release

Company name: DAIICHI SANKYO COMPANY, LIMITED

Representative: Takashi Shoda, President and Representative Director  
(Code no.: 4568, First Section, Tokyo, Osaka and Nagoya Stock Exchanges)

Please address inquiries to Toshio Takahashi, Corporate Officer in Charge,  
Corporate Communications Department  
Telephone: +81-3-6225-1126

**Completion of the Registration of Trial Subjects for ORIENT on the  
Suppressive Effects of the Angiotensin II Receptor Blocker Olmetec®  
against the Progression of Diabetic Nephropathy**

**Tokyo, October 12, 2005** – DAIICHI SANKYO COMPANY, LIMITED has announced that its 100% subsidiary company, Sakyo Co., Ltd. (President, Yasuhiro Ikegami), is implementing clinical trials in both Japan and Hong Kong entitled ORIENT which studies the suppressive effects of the antihypertensive drug Olmetec® (generic name: olmesartan medoxomil) against the progression of diabetic nephropathy, and has completed registration of trial subjects as of the end of September.

Diabetic nephropathy is one of the 3 major complications of diabetes. It is a disease which progresses from early stage confirmation of small traces of proteinuria, to overt nephropathy identified by overt proteinuria, and finally to renal failure and implementation of dialysis.

In Japan, the number of chronic dialysis patients in 2004 reached nearly 250,000, and 35,000 new dialysis patients were confirmed just last year alone. The main causative disease was diabetic nephropathy, accounting for 41.3% of new dialysis patients. The increase in dialysis patients due to diabetic nephropathy has been a cause for concern in Japanese medical circles. In fact, there were 7,459 new dialysis patients resulting from diabetic nephropathy in 1994, and this figure increased by about twofold in 2004 to 14,490 patients.

ORIENT targeted 400 Asian (including Japanese) patients exhibiting diabetic nephropathy which accompanies type 2 diabetes presenting overt proteinuria. It is an event trial which evaluates the suppression of the progression of diabetic nephropathy by olmesartan medoxomil. This trial administers olmesartan

medoxomil or a placebo over the long term toward overt nephropathy stage patients and tests whether the implementation of dialysis can be prevented or delayed by comparing the olmesartan medoxomil group and the placebo group. Moreover, this trial also sanctions the parallel use of the ACE inhibitor, and also tests the concomitant effectiveness of the angiotensin II receptor blocker together with the ACE inhibitor. This trial was implemented since 2003 in Japan and Hong Kong, and the trial results are scheduled to be released in 2009 when the average 4 year follow-up period comes to an end.

In order to suppress the progression of diabetic nephropathy, compound treatments such as treatment for high blood pressure among others is called for in addition to treatment for diabetes. It has been clinically confirmed that olmesartan medoxomil possesses strong antihypertensive activity. Again, the suppressive activity of the progression of diabetic nephropathy by olmesartan medoxomil has been confirmed in a non-clinical test using a rat, and it is being anticipated as an effective drug to counter diabetic nephropathy.

Apart from the ORIENT study, this company is currently implementing large-scale clinical trials in Europe entitled ROADMAP to verify the suppression of the onset of trace amounts of albuminuria. By simultaneously implementing ORIENT and ROADMAP, we shall verify the effectiveness of olmesartan medoxomil against the entire pathology of diabetic nephropathy from its onset until its advanced stages.

Olmesartan medoxomil is already being sold through 32 countries around the world including the United States, Germany, the U.K. and Brazil, among other nations, and is being sold in Japan under brand name Olmetec®.

\* Please refer to the separate sheet for an overview on ORIENT.

## Overview of ORIENT

### 1. Trial name

English: ORIENT (Olmesartan Reducing Incidence of End Stage renal stage in diabetic Nephropathy Trial)

Japanese: Olmesartan test to suppress the progression of diabetic nephropathy

### 2. Trial content

This trial targeted 400 diabetic nephropathy patients with mild and moderate renal disorder presenting proteinuria, secondary to type 2 diabetes. 10-40mg of olmesartan medoxomil or placebo was administered and a double-blind comparative test comparing the transition periods to renal multiple end points was conducted (doubling of serum creatinine, advanced nephropathy, death).

### 3. Implemented country/region: Japan, Hong Kong

### 4. Trial commencement: year 2003, second quarter

### 5. Average follow-up period: 4 years (scheduled)

### 6. Trial end: 2009 scheduled