

For Immediate Release

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**Announce on Amlodipine and Olmesartan Study Results Released**

The attached is the press release of Daiichi Sankyo, Inc., US affiliates of DAIICHI SANKYO COMPANY, LIMITED.



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**Amlodipine and Olmesartan Study Results Released;  
Late Breaker Presented at American Society of Hypertension  
Twenty-Second Annual Scientific Meeting (ASH 2007)**

***First Release of Data for New Combination***

**Parsippany, NJ (May 21, 2007)** -- Combining the calcium channel blocker amlodipine besylate with the angiotensin receptor blocker olmesartan medoxomil, produced significant mean reductions in seated systolic and diastolic blood pressure in patients with hypertension, according to data presented at the American Society of Hypertension's Twenty-Second Annual Scientific Meeting at Exposition (ASH 2007). The Phase III registration trial data was presented for the first time at today's "late breaker" session at the ASH meeting in Chicago. Daiichi Sankyo, Inc. filed a New Drug Application (NDA) in November 2006 for a fixed-dose combination of the two antihypertensives. This investigational agent of amlodipine besylate/olmesartan medoxomil (AZOR™) is under regulatory review in the United States, including trade name review.

"All combinations of amlodipine and olmesartan produced significantly greater mean reductions in both diastolic and systolic blood pressure than either medication alone," said Steven G. Chrysant, MD, of the Oklahoma Cardiovascular and Hypertension Center and the University of Oklahoma School of Medicine, and lead investigator on the study. "All combinations with amlodipine 10 mg demonstrated a lower incidence of edema versus amlodipine 10 mg monotherapy," he added.

Amlodipine 10mg/day plus olmesartan 40mg/day reduced systolic blood pressure an average of 30.1 mm Hg and the diastolic reading an average of 19.0 mm Hg. These results were in comparison with mean reductions of 19.7 mm Hg systolic/12.7 mm Hg diastolic for amlodipine 10mg alone (placebo= 4.8/3.1 mm Hg). When compared to amlodipine 10mg alone, amlodipine 10mg/day plus olmesartan 40 mg/day resulted in a 53 percent greater reduction in systolic blood

pressure. Amlodipine combined with olmesartan provides two complimentary mechanisms of action to lower blood pressure: calcium channel blockade with amlodipine and angiotensin receptor blockade with olmesartan.

The AE profile for each of the combinations was similar in nature to the monotherapy components. Most reported treatment-emergent adverse events across all treatment groups were considered mild in severity.

Hypertension, also known as high blood pressure, affects approximately 72 million people in the United States and approximately one billion worldwide. It is often difficult to control, and of those diagnosed with high blood pressure, 64.9 percent do not have the condition under control.<sup>1</sup>

### **Study Design**

The study was a Phase III, 8-week, randomized, double-blind, placebo-controlled, parallel-group, factorial study in 1,940 patients with mild to severe hypertension defined as seated diastolic BP between  $\geq 95$  mm Hg and  $\leq 120$  mm Hg. The purpose of the study was to determine if co-administration of amlodipine 5-10 mg/day and olmesartan 10-20-40 mg/day had a significant benefit vs. its respective monotherapy components. Primary and one of the secondary endpoints were mean change from baseline in seated diastolic and seated systolic blood pressure at week 8, respectively.

### **About Daiichi Sankyo, Inc.**

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Co., Ltd., Japan's second largest pharmaceutical company and a global leader in pharmaceutical innovation since 1899. The company is dedicated to the discovery, development and commercialization of innovative medicines that improve the lives of patients throughout the world.

The primary focus of Daiichi Sankyo's research and development is cardiovascular disease, including therapies for dyslipidemia, hypertension, diabetes, and acute coronary syndrome. The company is also pursuing the discovery of new medicines in the areas of glucose metabolic disorders, infectious diseases, cancer, bone and joint diseases, and immune disorders.

For more information, please visit [www.dsus.com](http://www.dsus.com).

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1. <http://www.americanheart.org/presenter.jhtml?identifier=4621> Site accessed 5/10/2007