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**FDA Approves Benicar[®] for the Treatment of High Blood Pressure in Children and Adolescents
aged 6-16¹**

***New Treatment Option Available for the Rapidly Growing Population of Children Suffering From
High Blood Pressure²***

Parsippany, NJ – February 11, 2010 – Daiichi Sankyo, Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved the hypertension treatment Benicar[®] (olmesartan medoxomil) for use in children and adolescents 6 to 16 years of age.³ Benicar was originally approved in 2002 for the treatment of hypertension in adults.

Approximately 5 percent – or 3.6 million – American children suffer from high blood pressure, with the majority unaware they have the condition.^{4,5} Studies have also found that the average blood pressure of American children is on the rise, in parallel with the increase of children's weight.⁶ In fact, an analysis of nearly 40 years of national surveys of high blood pressure trends in children and adolescents showed that the prevalence of elevated blood pressure among this group has been growing since the late 1980's.⁷

"As hypertension is on the rise also in a younger population, Daiichi Sankyo believes it is important to help doctors meet the challenge of treating these pediatric patients by providing a treatment option to help people effectively manage their hypertension," said Reinilde Heyrman, MD, Vice President Clinical Development – Operations, Daiichi Sankyo Pharma Development.

Pediatric hypertension is closely linked to childhood obesity, as obese children are at approximately a three-fold higher risk for hypertension than non-obese children.⁸ Additionally hypertension during childhood has been shown to be an independent risk factor for hypertension in adulthood, and to be associated with early markers of cardiovascular disease, making it important to treat this condition in children and adolescents.⁹

The approval of this expanded indication was based on a phase III study examining the antihypertensive effects of Benicar in pediatric patients. The study found Benicar to be safe and efficacious in children ages 6-16 with hypertension, resulting in blood pressure reductions that were statistically different in comparison to placebo. Benicar was generally well tolerated in pediatric patients, and the adverse event profile was similar to that for adults.¹⁰

Benicar is an angiotensin II receptor blocker (ARB), which blocks the action of a substance in the body called angiotensin II that increases blood pressure. It is indicated for the treatment of hypertension in adults as well as pediatric patients 6-16 years of age, alone or with other antihypertensive agents.¹¹

About Benicar®

Angiotensin II is a hormone that interacts with a receptor on arterial blood vessels, which results in constriction and increasing blood pressure. In addition, angiotensin II stimulates the release of another hormone that causes enhanced sodium and chloride (salt) retention, with a resultant increase in vascular water retention and blood volume that also contributes to an elevation in blood pressure. Benicar is a member of the ARB class of antihypertensive medications that help lower blood pressure by blocking the angiotensin II receptor on the blood vessels, which may lead to antagonizing the release of the hormone which causes salt retention and increased blood volume.

Benicar is indicated for the treatment of hypertension in adults and pediatric patients 6 to 16 years of age, alone or with other antihypertensive agents. Benicar may be used as initial therapy.

IMPORTANT SAFETY INFORMATION ABOUT BENICAR®

WARNING – AVOID USE IN PREGNANCY

When pregnancy is detected, discontinue Benicar as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus [see Warnings and Precautions (5.1)].

Hypotension in Volume- or Salt-Depleted Patients

In patients with an activated renin-angiotensin system, such as volume- and/or salt-depleted patients (eg, those being treated with high doses of diuretics), symptomatic hypotension may be anticipated after initiation of treatment with BENICAR®. Treatment should start under close medical supervision. If hypotension does occur, place the patient in the supine position and, if necessary, give an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further treatment, which usually can be continued without difficulty once the blood pressure has stabilized.

Impaired Renal Function

In studies of ACE inhibitors in patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen (BUN) have been reported. There has been no long-term use of BENICAR in patients with unilateral or bilateral renal artery stenosis, but similar results may be expected.

Adverse Reactions

In adults:

- The withdrawal rates due to adverse reactions were similar with BENICAR® to placebo: BENICAR (2.4% vs 2.7%)
- The incidence of adverse reactions with BENICAR was similar to placebo

- The only adverse reaction that occurred in >1% of patients treated with BENICAR[®] and more frequently than placebo was dizziness (3% vs 1%)
- The adverse experience profile in pediatric patients were similar to those seen in adults

Dosage and Administration

- No initial dosage adjustments are recommended with BENICAR in elderly or in moderate to marked renal impairment*/hepatic dysfunction
- In patients with possible depletion of intravascular volume (eg, patients treated with diuretics, particularly with impaired renal function), initiate BENICAR under close medical supervision and give consideration to use of a lower starting dose

*Creatinine clearance <40 mL/min.

Please see full prescribing information for BENICAR.

ABOUT DAIICHI SANKYO, INC.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Tokyo-based Daiichi Sankyo Co., Ltd., which is a global pharmaceutical innovator. The headquarters company was established in 2005 from the merger of two leading Japanese pharmaceutical companies. This integration created a more robust organization that allows for continuous development of novel drugs for patients around the world. A central focus of Daiichi Sankyo's research and development is cardiovascular disease, including therapies for dyslipidemia, hypertension, diabetes and acute coronary syndrome. Also important to the company is the discovery of new medicines in the areas of infectious diseases, cancer, bone and joint diseases, and immune disorders. For more information, visit www.dsi.com.

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¹ Daiichi Sankyo. Benicar Prescribing Information.

² Din-Dzietham, R et al. High Blood Pressure Trends in Children and Adolescents in National Surveys, 1963 to 2002. *Circulation*. 2007;116:1488-1496.

³ Daiichi Sankyo. Benicar Prescribing Information.

⁴ Hansen, M et al. Underdiagnosis of Hypertension in Children and Adolescents. *JAMA*. 2007;298(8):874-879.

⁵ U.S. Census Bureau. Age: 2000. Census 2000 Brief. Available at <http://www.census.gov/prod/2001pubs/c2kbr01-12.pdf>. Accessed on January 6, 2010.

⁶ Hansen, M et al. Underdiagnosis of Hypertension in Children and Adolescents. *JAMA*. 2007;298(8):874-879.

⁷ Din-Dzietham, R et al. High Blood Pressure Trends in Children and Adolescents in National Surveys, 1963 to 2002. *Circulation*. 2007;116:1488-1496.

⁸ Hypertension. "Obesity Hypertension in Children: A Problem of Epidemic Proportions." Jonathan Sorof; Stephen Daniels. October 2002;40:441. Available at: <http://hyper.ahajournals.org/cgi/content/short/40/4/441>. Accessed on October 21, 2009.

⁹ Hansen, M et al. Underdiagnosis of Hypertension in Children and Adolescents. *JAMA*. 2007;298(8):874-879.

¹⁰ Daiichi Sankyo. Benicar Prescribing Information.

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