For more information, please contact:

Alyssa Dargento
Daiichi Sankyo, Inc.
(973) 944-2913
(973) 727-1604 (cell)
adargento@dsi.com

Matthew Gold
Hill & Knowlton
(212) 885-0564
(631) 804-3639 (cell)
matthew.gold@hillandknowlton.com

New Data Shows Blood Pressure Reduction Therapy with BENICAR® and BENICAR HCT® Effectively Reduces Blood Pressure in Elderly Patients to Target Blood Pressure

Parsippany, NJ – May 8, 2009 – Daiichi Sankyo, Inc. announced today that new data presented at the American Society of Hypertension, Inc. (ASH) Annual Scientific Meeting and Exposition (ASH 2009) in San Francisco from the **BeniSILVER** study found that BENICAR® and BENICAR HCT® provided a mean reduction in 24-hour ambulatory systolic blood pressure (SBP) of 25.7 mm Hg among patients with an average age of 72 years, demonstrating efficacy without compromising safety. Patients age 65 years and older also saw their 24-hour ambulatory diastolic blood pressure (DBP) drop a mean of 12.3 mm Hg. The BeniSILVER study was designed to investigate the safety and blood pressure (BP)-lowering efficacy of BENICAR and BENICAR HCT in patients age 65 and older with mild to moderate (Stage 1) or challenging (Stage 2) hypertension.

Studies have found that both the prevalence and severity of hypertension increase as people get older, making it critical to achieve strict BP control in elderly populations.[1] In fact, in 2008, the **HY**pertension in the **V**ery **E**lderly **T**rial (HYVET) demonstrated that decreasing BP in the elderly can have significant benefits in reducing the incidence of heart failure, heart attack and stroke.[2] BENICAR and BENICAR HCT are indicated for the treatment of hypertension. There are no studies with either treatment demonstrating a reduction in cardiovascular events.

In the BeniSILVER study, researchers evaluated the percent of elderly patients achieving mean 24-hour ambulatory BP targets of <135/85, <130/80 and <120/80 mm Hg. ABPM is generally considered a better indicator of target organ injury than cuff measurement, since it provides a 24-hour measurement of patient BP.[3] BENICAR and BENICAR HCT were able to safely and effectively achieve a 24-hour ambulatory target blood pressure of <135/85 mm Hg in 83 percent of elderly patients (age 65 and older). In addition, 73 percent and 44 percent reached the ambulatory targets of <130/80 mm Hg and <120/80 mm Hg, respectively.

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"The ability of Benicar® to bring elderly patients to blood pressure targets is very important, since attaining blood pressure targets can be so challenging in this group," said Dr. Joel M. Neutel, MD, director, Orange County Heart Institute and Research Center. "Although some physicians may be reluctant to use aggressive treatments for fear of an increased risk of adverse events, the findings show hypertension treatment can be accomplished safely and effectively in the elderly."

Benicar was well tolerated by elderly patients, with only nine of the initial 178 patients discontinuing treatment because of treatment emergent adverse events (AEs). In this trial, occurrence of drug-related AEs included: dizziness (3.4 percent), hypotension (2.2 percent), and/or headache (1.1 percent).

High blood pressure can cause permanent changes to blood vessels and the heart that may create serious problems elsewhere in the body.[4] Hypertension is one of the most prevalent conditions in the United States, affecting approximately one in three American adults (about 73 million people age 20 and older) and approximately one billion people worldwide.[5,6] It is often difficult to control, and of those with high blood pressure, approximately 55 percent do not reach recommended BP levels.[7] The number of people with high blood pressure is expected to reach about 1.6 billion worldwide by 2025.[8]

Patients Older Than 75

A sub analysis of the trial found that 82.5 percent and 67.5 percent of patients over age 75 treated with BENICAR and BENICAR HCT® were able to achieve an ambulatory BP target of <135/85 and <130/80 mm Hg, respectively. Adverse events were also found to be similar for patients above and below 75 years of age.

About the BeniSILVER Study

BeniSILVER was a 14-15 week, prospecitve, open-label, single-arm, dose-titration, study to investigate the safety and BP-lowering efficacy of the proposed titration of olmesartan medoxomil and olmesartan medoxomil/hydrochlorothiazide in 178 patients age 65 years or older with mild to moderate (Stage 1) or challenging (Stage 2) hypertension. Following a 2-3 week placebo period, 176 patients started olmesartan (OM) 20 mg. If SBP remained ≥120 mm Hg or DBP remained ≥70 mm Hg, patients were titrated at 3-week intervals until BP was normalized as follows: OM 40mg, olmesartan medoxomil/hydrochlorothiazide (OM/HCTZ) 40mg/12.5mg and OM/HCTZ 40mg/25mg. Patients (asymptomatic) with BP <120/70 mm Hg continued on their current assigned dose (maintenance treatment) unless BP was uncontrolled, SBP ≥140mm Hg and/or DBP ≥90 mm Hg, at which time the titration schedule was resumed.

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The primary endpoint was change in mean SBP from baseline after 12 weeks of treatment as measured by a 24-hour ABPM. The secondary endpoints included change from baseline in mean 24-hour ambulatory DBP, change from baseline in mean SeSBP and SeDBP and proportion of patients achieving BP goal (<140/90, <135/85, <130/80 & <120/80 mm Hg), at each titration period and study end and a subgroup analysis by age (≥75 years or >75 years). Mean baseline ABPM was 148.8/80.9 mm Hg and mean baseline seated BP was 165.5/87.7 mm Hg, indicating predominant systolic hypertension in this elderly patient cohort with a mean age of 71.9 years and 65.9 percent challenging (Stage 2) hypertension.

Treatment emergent adverse events (TEAE) were seen in 56 patients, 32.6% of the treatment population. The most common were dizziness (8 patients, 4.5%) diarrhea (4 patients, 2.2%), upper respiratory tract infection (4 patients, 2.2%), headache (4 patients, 2.2%), and hypotension (4 patients, 2.2%). Among individual treatment regimens, headache (4 patients, 2.4%) and dizziness (4 patients, 2.4%) were reported for OM 40 mg and dizziness (6 patients, 3.8%) was reported for OM/HCTZ 40/12.5 mg. Nine patients (5.1%) discontinued participation in the study due to TEAE.

The results of this open-label trial differ from those obtained in the pivotal, placebo-controlled US MATRIX trial.

About BENICAR® and BENICAR HCT®

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 and antagonizing the release of the hormone which causes salt retention and increased blood volume. BENICAR HCT® combines BENICAR® with the diuretic hydrochlorothiazide.

BENICAR and BENICAR HCT are indicated for the treatment of hypertension. They may be used alone or in combination with other antihypertensive agents. BENICAR HCT is not indicated for initial therapy.

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IMPORTANT SAFETY INFORMATION ABOUT BENICAR® and BENICAR HCT®

USE IN PREGNANCY

When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, BENICAR or BENICAR HCT should be discontinued as soon as possible**. See WARNINGS, Fetal/Neonatal Morbidity and Mortality** in the prescribing information**.**

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 occur after initiation of treatment with BENICAR. Treatment should start under close medical supervision. If hypotension does occur, the patient should be placed in the supine position and, if necessary, given 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 olmesartan medoxomil in patients with unilateral or bilateral renal artery stenosis, but similar results may be expected.

The prescribing information for BENICAR HCT also includes the following warnings regarding its hydrochlorothiazide component:

BENICAR HCT is not recommended in patients with severe renal impairment and is contraindicated in patients with anuria or hypersensitivity to other sulfonamide derived drugs

Fetal/Neonatal Morbidity and Mortality

Thiazides cross the placental barrier and appear in cord blood. There is a risk of fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions that have occurred in adults.

Hepatic Impairment

Thiazides should be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Hypersensitivity Reaction

Hypersensitivity reactions to hydrochlorothiazide may occur in patients with or without a history of allergy or bronchial asthma, but are more likely in patients with such a history.

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Systemic Lupus Erythematosus
Thiazide diuretics have been reported to cause exacerbation or activation of systemic lupus erythematosus.

Lithium Interaction
Lithium generally should not be given with thiazides.

Adverse Events
● The withdrawal rates due to adverse events (AEs) were similar with BENICAR® and BENICAR HCT® to placebo: BENICAR (2.4% vs 2.7%); BENICAR HCT (2.0% vs 2.0%)
● The incidence of AEs with BENICAR and BENICAR HCT was similar to placebo

— The only AE that occurred in >1% of patients treated with BENICAR® and more frequently than placebo was dizziness (3% vs 1%)
— AEs reported in >2% of patients taking BENICAR HCT® and more frequently than placebo included nausea (3% vs 0%), hyperuricemia (4% vs 2%), dizziness (9% vs 2%), and upper respiratory tract infection (7% vs 0%)

Dosing 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 on diuretics, particularly with impaired renal function), BENICAR should be initiated under close medical supervision and consideration given to use of a lower starting dose
● For BENICAR HCT, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range

*Creatinine clearance <40 mL/min.

Please see full prescribing information for BENICAR and BENICAR HCT.

About Daiichi Sankyo

A global pharma innovator, Daiichi Sankyo Co., Ltd., was established in 2005 through the merger of two leading Japanese pharmaceutical companies. This integration created a more robust organization that allows for continuous development of novel drugs that enrich the quality of life for patients around the world. A central focus of Daiichi Sankyo's research and development are thrombotic disorders, malignant neoplasm, diabetes mellitus, and autoimmune disorders. Equally important to the company are hypertension, hyperlipidemia or atherosclerosis and bacterial infections. For more information, visit www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is the U.S. subsidiary of Daiichi Sankyo Co., Ltd. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

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[1] Lloyd-Jones DM, Evans JC, Levy D. Hypertension in adults across the age spectrum: current outcomes and control in the community. *JAMA*. 2005;294:466-472

[2] Beckett, et al. Treatment of Hypertension in Patients 80 Years of Age or Older**.** *N Engl J Med*. 2008;358;1887-98

[3] National High Blood Pressure Education Program, JNC 7: The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure, December, 2003. pg. 19.

[4] National Heart, Lung and Blood Institute, High Blood Pressure Key Points. Available at: http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP_Summary.html. Accessed August 28, 2008

[5] American Heart Association. 2004 High Blood Pressure Statistics. Available at: http://www.americanheart.org/presenter.jhtml?identifier=4621. Accessed August 27, 2008

[6] Chobanian AV, Bakris GL, Black HR et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *JAMA*. 2003;289:2560-2572

[7] American Heart Association. 2004 High Blood Pressure Statistics. Available at: http://www.americanheart.org/presenter.jhtml?identifier=4621. Accessed August 28, 2008.

[8] Kearney PM, et al. Global burden of hypertension: analysis of worldwide data. *Lancet* 2005, 365:217-23.