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New Data Shows 45 Percent of Patients with Stage 1 Hypertension Reached Normotension with BENICAR® and BENICAR HCT®

Data Presented at the American Society of Hypertension's Twenty-Third Annual Scientific Meeting

- *A cumulative forty-five percent (45%) of patients with stage 1 hypertension treated with a regimen of BENICAR® (olmesartan medoxomil) and BENICAR HCT® (olmesartan medoxomil/hydrochlorothiazide) achieved normotension (<120/80 mm Hg) (placebo:1.4%).*
- *Eight out of 10 (cumulative 81%) patients with stage 1 hypertension were able to reach a goal blood pressure (BP) of <140/90 mm Hg on BENICAR and BENICAR HCT (placebo: 43.1%).*
- *Six out of 10 (cumulative 60.3%) patients with stage 1 hypertension were able to achieve a BP of <130/80mm Hg when treated with BENICAR and BENICAR HCT (placebo: 6.9%).*

Parsippany, NJ (May 14, 2008) – Daiichi Sankyo, Inc. announced today that data presented at the American Society of Hypertension's Twenty-Third Annual Scientific Meeting (ASH 2008) in New Orleans demonstrates that a cumulative 45 percent of patients with stage 1 hypertension treated with a regimen of BENICAR® (olmesartan medoxomil) and BENICAR HCT® (olmesartan medoxomil/ hydrochlorothiazide) were able to safely and effectively achieve a normotensive blood pressure, <120/80 mm Hg (placebo: 1.4%) . The Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7) defines this level as normotension.

The 15-16 week, double-blind, randomized, placebo controlled titration study conducted with 276 patients with Stage 1 and Stage 2 hypertension further demonstrated in a sub analysis that eight out of ten (cumulative 81%) patients with stage 1 hypertension were able to reduce their blood pressure to the <140/90 mm Hg goal recommended by JNC 7 for patients (placebo: 43.1%). The study also demonstrated that six out of 10 (cumulative 60.3%) patients with stage 1 hypertension were able to reach a more aggressive BP target of <130/80 mm Hg (placebo: 6.9%). In addition, in another sub analysis, the study demonstrated that nearly seven out of ten (cumulative 69%) with stage 2 hypertension were able to reach the <140/90 mm Hg blood

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pressure goal recommended by the JNC 7 (placebo: 16.9%). Stage 1 hypertension is defined by the JNC 7 as systolic blood pressure (SBP) of 140-159 mm Hg or diastolic blood pressure (DBP) of 90-99 mm Hg; Stage 2 hypertension is defined as 160/100 mm Hg or higher.¹

“These results are very encouraging as we in the cardiovascular community have been advocating to more aggressively fight hypertension,” said Suzanne Oparil M.D., Director, Vascular Biology & Hypertension Program, University of Alabama at Birmingham, lead investigator of the study and President of ASH. “The study showed the ability of a regimen of BENICAR and BENICAR HCT to lower blood pressure beyond 140/90 mm Hg to the more aggressive normotensive target.”

In the overall study, both stage 1 and stage 2 patients receiving BENICAR HCT 40/25 mg saw their seated systolic blood pressure (SeSBP) drop a mean of 23 mm Hg from a mean SBP baseline of 158 mm Hg (placebo: -2.6 mm Hg). In addition, more than one in four patients (27 percent) reached normotension, defined as <120/80 mm Hg (placebo: 1.5%).

Of this study patient population, those with stage 2 hypertension achieved very good results with this regimen of BENICAR and BENICAR HCT. Of those titrated up to the maximum dose of 40/25mg, a cumulative 69 percent achieved a BP of <140/90 mm Hg (placebo: 17%) while a cumulative 15 percent achieved a BP of <120/80 mm Hg (placebo: 1.5%). For those with stage 2 hypertension, the average BP reduction for those patients on BENICAR 40/25 mg was 25/14 mm Hg (placebo: 6.2/1.9 mm Hg).

Hypertension, also known as high blood pressure, affects approximately 73 million people in the United States and approximately one billion worldwide.^{2,3} Called the “silent killer” because it often has no specific symptoms, hypertension increases the risk of cardiovascular and related diseases such as stroke, heart attack, heart failure and kidney disease.⁴ Of those diagnosed with high blood pressure, 64.9 percent did not have the condition under control.⁵

Study Design

The study was a double-blind, randomized, placebo-controlled, parallel-group, multi-center titrate-to-goal study. The primary endpoint was change from baseline in mean SBP at study end. The secondary endpoints included change from baseline in mean DBP, and the percent of patients achieving BP goals of <140/90, <130/85, <130/80 and <120/80 mm Hg at each titration period and study end and a subgroup analysis by baseline stage of hypertension (Stage 1 and Stage 2). Overall mean baseline BP was 157/94 and 155/94 mm Hg for the active treatment and placebo group, respectively.

The patient population of 465 initially entered a 3–4 week single-blind placebo run-in period. Patients who met inclusion criteria (n=276) were then randomized to receive olmesartan (OM) or placebo according to a titration scheme consisting of a 12-week double-blind study period. Patients randomized to olmesartan initially received 20 mg/day. If BP remained \geq 120/80 mm Hg, patients were uptitrated until BP was normalized. The titration schedule was as follows: OM 40 mg/day (week 4–6), OM/HCTZ 40/12.5 mg/day (week 7–9), and OM/HCTZ 40/25 mg/day

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(week 10–12). Once BP was controlled to the target level, patients stayed on the medication dosage that achieved this goal. If at any point, patients BP exceeded 120/80, the titration schedule was resumed.

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.

Important Safety Information

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 (e.g., 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.

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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.

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

In clinical trials, the withdrawal rates due to adverse events (AEs) were similar with BENICAR and BENICAR HCT to placebo: BENICAR (2.4 percent vs 2.7 percent); BENICAR HCT (2.0 percent vs 2.0 percent). The incidence of AEs with BENICAR and BENICAR HCT were similar to placebo. The only AE that occurred in >1 percent of patients treated with BENICAR and more frequently than placebo was dizziness (3 percent vs 1 percent). AEs reported in >2 percent of patients taking BENICAR HCT and more frequently than placebo included nausea (3 percent vs 0 percent), hyperuricemia (4 percent vs 2 percent), dizziness (9 percent vs 2 percent), and upper respiratory tract infection (7 percent vs 0 percent).

No initial dosage adjustments are recommended with BENICAR in elderly, in moderate to marked renal impairment (creatinine clearance <40 mL/min), or in hepatic dysfunction. In patients with possible depletion of intravascular volume (e.g., patients on diuretics, particularly with impaired renal function), BENICAR should be initiated under close medical supervision and

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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.

Please see full prescribing information for BENICAR and BENICAR HCT.

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.

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1 JNC 7 = The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7), which issued new guidelines in 2003 for hypertension prevention and management.

2 <http://www.americanheart.org/presenter.jhtml?identifier=4621> Site accessed 4/18/2008

3 Kearney, P. et al. "Global Burden of Hypertension: Analysis of Worldwide Data." *Lancet* 2005; 365: 217-23

4 <http://www.americanheart.org/presenter.jhtml?identifier=2114> Site accessed 4/18/2008

5 <http://www.americanheart.org/presenter.jhtml?identifier=4621> Site accessed 4/18/2008