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Ongoing Landmark ROADMAP Study Demonstrates Significant Improvement in Blood Pressure Control at One Year, According to Blinded Results

First-Ever Trial to Evaluate Whether Olmesartan Medoxomil Prevents Onset of Early Kidney Disease in Type 2 Diabetes Patients

San Francisco, CA – May 8, 2009 – Blinded one-year blood pressure (BP) reduction data from the ongoing landmark study **ROADMAP** (**R**andomized **O**lmesartan **A**nd **D**iabetes **M**icro**A**lbuminuria **P**revention), were presented today at the American Society of Hypertension (ASH) Twenty-Fourth Annual Scientific Meeting and Exposition (ASH 2009) in San Francisco. ROADMAP is the first-ever large-scale clinical trial, being conducted in 19 European countries to evaluate whether the angiotensin II receptor blocker (ARB) olmesartan medoxomil can prevent the onset of microalbuminuria in patients with type 2 diabetes (T2DM). Microalbuminuria is an early sign of kidney disease, as well as an important risk factor of cardiovascular disease (CVD).[1] The secondary objective of the ROADMAP trial includes incidence of cardiovascular and renal morbidity and mortality. A qualitative parameter in the secondary objective was to measure cuff blood pressure (BP).

The double-blinded one-year data presented at ASH 2009 showed that a strict BP control (<130/80) regimen in the ROADMAP trial improved BP compared to baseline in T2DM patients. The data presented represents the blinded total patient population, which includes patients randomized either to olmesartan or placebo in addition to standard antihypertensive treatment (excluding RAS inhibition). After one year of treatment, 61 percent of patients in ROADMAP achieved the recommended BP goal of <130/80 mm Hg, a significant increase from a baseline of 28 percent controlled. The prevalence of Stage 1 and Stage 2 hypertension decreased from 32

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to 11 percent from 9 to 2 percent, respectively. ROADMAP was designed to allow analysis of BP responses and potential renal and CVD risk benefits across a wide range of patients with diabetes classified from normotension to hypertension, and to test whether this extensive subgrouping might provide additional insight for practicing physicians.

"It is essential to manage blood pressure very aggressively in diabetics because their heart attack and stroke rates are more closely related to their blood pressure levels than to their blood sugar levels," said Joseph L. Izzo, Jr., M.D., Professor of Medicine and Pharmacology at SUNY-Buffalo and Director of Medicine at the Erie County Medical Center in Buffalo. "In ROADMAP, to date, we have achieved some of the lowest BP levels ever in a clinical trial.

About ROADMAP

ROADMAP is a randomized, double-blind, placebo-controlled, parallel-group, multi-center Phase III study being conducted at 262 collaborating centers in 19 European countries. The primary goal of the study is to test the hypothesis that treatment of T2DM patients with 40 mg of olmesartan medoxomil will prevent or delay the occurrence of microalbuminuria in comparison to a regimen that excludes agents that directly block the RAS. The secondary objective is to test the hypothesis that treatment with olmesartan medoxomil has a positive effect on cardiovascular and renal morbidity and mortality.

The study involves 4,449 men and women with T2DM with normoalbuminuria ($\leq$35 mg albumin/g urine creatinine for women and $\leq$ 25 mg albumin/g urine creatinine for men) at the outset, and who have at least one additional cardiovascular risk factor, including patients being treated for hypertension. Patients were randomized to receive 40 mg of olmesartan medoxomil or placebo for an average of five years. Patients with hypertension were also treated at the investigator's discretion with diuretics, alpha- or beta-blockers or calcium channel antagonists to achieve a target BP of <130/80. Patients requiring treatment with an ARB or ACEi were withdrawn from the study.

About the ROADMAP One-Year Results

According to baseline blood pressures of the overall patient population, patients were categorized into the following JNC 7 classifications: normal, pre-hypertension, Stage 1 and Stage 2 hypertension. Mean BP for the overall population at study randomization was 136.2/80.6 mm Hg. In the 4,013 patients who remained on double-blind treatment with either olmesartan medoxomil therapy or placebo after one year, mean systolic BP reduction was 9.4 mm Hg, though responses were highly dependent on JNC 7 stages at outset. The ROADMAP study also showed a decrease in the prevalence of Stage 1 hypertension from 32 to 11 percent, as well as

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decrease in the prevalence of Stage 2 hypertension from 9 to 2 percent. In addition, the prevalence of normotension increased from 11 to 22 percent.

About Diabetes, Microalbuminuria and Hypertension

According to the World Health Organization (WHO), the number of people who have diabetes worldwide was approximately 170 million people in 2000, with that number anticipated to more than double by the year 2030.[2] Accounting for about 90 percent of diabetes cases worldwide, type 2 diabetes results from the body's inability to respond properly to the action of insulin produced by the pancreas.[3]

Diabetes is among the leading causes of kidney failure.[4] High blood sugar levels and high blood pressure (often present in patients with type 2 diabetes), may result in small amounts of albumin, a plasma protein, leaking into the urine. This microalbuminuria is an early sign of kidney dysfunction, and is a strong independent risk factor for cardiovascular disease.[5]

Hypertension, or high blood pressure, is a major factor for the development and acceleration of kidney disease in people with diabetes.[6] The JNC 7, American Diabetes Association (ADA), the American Society of Hypertension (ASH) and the European Society of Hypertension (ESH) all recommend that physicians aim to control blood pressure in patients with type 2 diabetes to a level below 130/80 mm Hg (systolic/diastolic).[7, 8, 9]

About Olmesartan Medoxomil

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. Olmesartan medoxomil 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.

Olmesartan medoxomil is available in the United States under the brand name Benicar®. Benicar is indicated for the treatment of hypertension. Benicar may be used alone or in combination with other antihypertensive agents.

IMPORTANT SAFETY INFORMATION ABOUT BENICAR

USE IN PREGNANCY

When used in pregnancy during the second and third trimesters, drugs that act directly on

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the renin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, BENICAR® 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.

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

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

*Creatinine clearance <40 mL/min.

Please see full prescribing information for BENICAR.

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

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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.

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[4] Ibid.
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