For more information, please contact:

John Radziejewski
Hill & Knowlton
(212) 885-0412
(917) 238-8030 (cell)
john.radziejewski@hillandknowlton.com

Jason Ford
Daiichi Sankyo, Inc.
(973) 359-2634
(908) 868-4554 (cell)
jaford@dsus.com

AZOR™ Receives FDA Approval for Treatment of High Blood Pressure

Powerful New Combination Treatment Option Reduces Mean Systolic Blood Pressure Up to 30 Points

Parsippany, NJ – September 27, 2007 – Daiichi Sankyo, Inc. announced today that the United States Food and Drug Administration (FDA) has approved AZOR™ (amlodipine and olmesartan medoxomil) for the treatment of hypertension, also known as high blood pressure. AZOR is a convenient, once daily, single tablet combination of amlodipine, the number one prescribed calcium channel blocker (CCB) on the market[1], and olmesartan medoxomil, the active ingredient in Benicar®, which is the fastest growing angiotensin receptor blocker (ARB).[2] The combination of these two medications will give doctors a powerful new treatment option for patients with hypertension who need to reduce their blood pressure levels or who are uncontrolled on other medications.

In clinical trials, AZOR produced significant mean reductions in seated systolic and diastolic blood pressure in patients with hypertension. According to the pivotal registrational trial, AZOR 10/40 mg 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 10 mg alone (placebo= 4.8/3.1 mm Hg). When compared to amlodipine 10 mg alone, AZOR 10/40 mg resulted in a 53 percent greater reduction in the mean change of systolic blood pressure.

"AZOR is a valuable treatment addition, since so many people in the United States with hypertension do not have their blood pressure adequately controlled,"[3] said Michael A. Weber, MD, Professor of Medicine, State University of New York, Downstate College of Medicine. "AZOR with its established efficacy and favorable side effect profile provides two complementary mechanisms of action to lower blood pressure. It will give physicians a new treatment option for patients whose blood pressure remains too high on currently prescribed medications."

AZOR combines the complementary actions of the powerful CCB amlodipine which inhibits the entrance of calcium into the blood vessel walls, with olmesartan medoxomil, which blocks angiotensin II receptors. Angiotensin II is a hormone that causes blood vessels to tighten and narrow. Together the two medicines relax the blood vessels so that blood can flow more easily. Benicar (olmesartan medoxomil), Daiichi Sankyo's flagship ARB product, is the fastest growing medication in the fastest growing class of blood pressure-lowering drugs.[4]

"The approval of AZOR represents an important milestone for our growing U.S. organization and underscores our continued commitment to helping more patients reach their recommended blood pressure treatment goals," said Joseph P. Pieroni, President and CEO of Daiichi Sankyo, Inc.

High blood pressure can cause permanent changes to blood vessels and the heart that may create serious problems elsewhere in the body.[5] Hypertension is one of the most prevalent conditions in the United States affecting approximately one in three American adults and approximately one billion people worldwide.[6,7] It is often difficult to control, and of those diagnosed with high blood pressure, approximately 65 percent do not have the condition under control.[8] The number of people with high blood pressure is expected to reach about 1.6 billion worldwide by 2025.[9]

AZOR is indicated for the treatment of hypertension, alone or with other antihypertensive agents. AZOR is not indicated for the initial therapy of hypertension.

Daiichi Sankyo, Inc. and Forest Laboratories, Inc. signed a letter of intent in August to co-promote AZOR in the United States.

IMPORTANT SAFETY INFORMATION ABOUT AZOR

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, AZOR should be discontinued as soon as possible. See **WARNINGS AND PRECAUTIONS, Fetal/Neonatal Morbidity and Mortality**.

In volume- and/or salt-depleted patients, symptomatic hypotension due particularly to the olmesartan component may occur after initiation of treatment with AZOR. Treatment should start under close medical supervision.

Patients, particularly those with severe obstructive coronary artery disease, may develop increased frequency, duration, or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy.

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 effects would be expected with AZOR because of the olmesartan medoxomil component.

Since amlodipine is extensively metabolized by the liver and the plasma elimination half-life ($t_{1/2}$) is 56 hours in patients with severely impaired hepatic function, caution should be exercised when administering AZOR to patients with severe hepatic impairment.

The only adverse events that occurred in greater than 3% of patients treated with AZOR and more frequently than placebo were edema (22.2% vs.12.3%).

IMPORTANT SAFETY INFORMATION ABOUT BENICAR

Benicar is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

USE IN PREGNANCY

When used in pregnancy, during the second and third trimester, drugs that act directly on 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 (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.

Adverse Events

The withdrawal rates due to adverse events (AEs) were similar with Benicar to placebo: (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 (e.g., 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

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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Please see accompanying full prescribing information for AZOR and Benicar

* Creatinine clearance <40mL/min.

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[1] http://www.norvasc.com -- Last accessed October 12, 2006
[2] Data are representing May 2002 - February 2006 from IMS Health. National Prescription Audit, February 2006
[3] American Heart Association. 2004 High Blood Pressure Statistics
http://www.americanheart.org/presenter.jhtml?identifier=4621 Site accessed 8/1/2007
[4] Data are representing May 2002 - February 2006 from IMS Health. National Prescription Audit, February 2006
[5] National Heart, Lung and Blood Institute, High Blood Pressure Key Points.
http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP_Summary.html. Accessed August 1, 2007
[6] American Heart Association. 2004 High Blood Pressure Statistics.
http://www.americanheart.org/presenter.jhtml?identifier=4621. Accessed August 1, 2007
[7] 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
[8] American Heart Association. 2004 High Blood Pressure Statistics
http://www.americanheart.org/presenter.jhtml?identifier=4621 Site accessed 8/1/2007
[9] Kearney PM, et al. Global burden of hypertension: analysis of worldwide data. Lancet 2005, 365:217-23