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AZOR™ REDUCES BLOOD PRESSURE IN DIFFICULT TO TREAT SPECIAL POPULATIONS

Blood pressure reductions demonstrated in Blacks, Hispanics/Latinos, People with Diabetes and Obese Individuals

Parsippany, NJ (May 15, 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 demonstrated that the powerful combination drug AZOR™ (amlodipine and olmesartan medoxomil) safely and effectively helped patients across several major subpopulations lower their blood pressure (BP). An analysis of patient subgroups from the pivotal registrational trial demonstrated the efficacy of AZOR in several key difficult to treat patient groups including people of African and Hispanic/Latino descent, people with high body mass index (BMI) and those with diabetes.

The subgroup analyses were based on data from a pivotal, randomized, double-blind, placebo-controlled factorial design study conducted in 1,940 pts with mild to severe hypertension (SeDBP)* 95-120 mm Hg) to determine if amlodipine (AML) 5-10mg/day plus olmesartan (OM) 10-40 mg/day for eight weeks is more efficacious in reducing BP versus monotherapy components. The groups were chosen because each population generally have either poor control rates (Blacks and Hispanic/Latinos), [1,2] are difficult to control (people with high BMI)[3] or require lower blood pressure to achieve control (those with diabetes).[4]

"As we know, hypertension affects many people from all walks of life," said Suzanne Oparil, M.D., Director, Vascular Biology & Hypertension Program, University of Alabama at Birmingham, an investigator in the study and President of ASH. "No two patients are alike, nor do any two people present in the exact same way. This study has demonstrated that AZOR is an important tool for physicians to consider when treating hypertensive patients of different

* SeDBP = Seated Diastolic Blood Pressure. According to the JNC 7, a SeDBP between 90 and 99 is considered stage 1 hypertension and 100 and above is considered stage 2 hypertension.

ethnicities and health characteristics, as well as the more difficult to treat populations, such as people with diabetes."

Hypertension, also known as high blood pressure, affects approximately 72 million people in the United States and approximately one billion worldwide.[5,6] 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.[7] Of those diagnosed with high blood pressure, 64.9 percent do not have the condition under control.[8]

ABOUT THE ANALYSES

RACE/ETHNICITY

Blood pressure control in patients with hypertension remains unsatisfactorily low in the US, particularly in Black and Hispanic/Latino populations, with fewer than 30% of patients in these minority groups treated to goal BP.[9,10] Guidelines acknowledge that combination therapy will be required for the majority of patients to attain BP goals, and recommend that combination therapy utilizing agents from complimentary drug classes should be considered when BP is difficult to control or there is high cardiovascular risk, such as in minority patient populations.[11,12,13]

Of the 1,940 patients who entered the eight week pivotal study, 1,459 were non-Black and 474 were Black. Further, ethnicity was asked separately from race: 245 patients were Hispanic/Latino. All subgroups were matched for baseline BP of 164/102 mm Hg. AZOR 10/40 mg demonstrated a 29/16 mm Hg mean reduction in the Black cohort vs. 31/20 mm Hg in non-blacks. Further, in the Hispanic/Latino study patient population, AZOR 10/40 mg demonstrated a mean reduction of 29/21 mm Hg compared to 30/19 mm Hg in non-Hispanic/non-Latino.

BMI

A higher body mass index (BMI) often makes it more difficult for patients with hypertension to achieve target BP.[14] The analysis of data from the pivotal study demonstrated the ability of AZOR to produce substantial reductions in BP compared to the monotherapy components, regardless of BMI levels. For those patients with BMI $\geq$30 kg/m^2, AZOR 10/40 mg demonstrated mean reductions of 30/18 mm Hg from an average baseline BP of 163/102 in the total cohort. Patients with BMI of <30 kg/m^2 saw BP reductions of 31/21 mm Hg when treated with AZOR 10/40 mg from an average baseline BP of 165/101 in total cohort.

DIABETES

Patients with hypertension and diabetes are at greater risk of cardiovascular and renal disease and consequently have a more stringent recommended target BP goal of <130/80 mm

Hg. Most patients require treatment with a combination of at least two antihypertensive agents in order to achieve their recommended goal BP, especially high-risk subgroups, and use of complementary antihypertensive drug classes is advocated in such patients.[15,16]

Of the 1,940 patients who entered the eight week pivotal study, 261 had a medical history of diabetes. The data demonstrated the ability of AZOR to reduce blood pressure in the diabetes patient cohort. The diabetic patients treated with AZOR 10/40 mg were able to reduce their mean BP 30/18 mm Hg from an average baseline BP of 169/101 in the total cohort. This result was similar in comparison to patients without diabetes treated with AZOR 10/40 mg who were able to reduce their mean BP 30/19 mm Hg from an average baseline BP of 163/102 in the total cohort.

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

Hypotension in Volume- or Salt-Depleted Patients

In patients with an activated renin-angiotensin system, such as 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.

Vasodilation

Since the vasodilation attributable to amlodipine in AZOR is gradual in onset, acute hypotension has rarely been reported after oral administration. Nonetheless, caution, as with any other peripheral vasodilator, should be exercised when administering AZOR, particularly in patients with severe aortic stenosis.

Severe Obstructive Coronary Artery Disease

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 or at the time of dosage increase.

Congestive Heart Failure

In general, calcium channel blockers should be used with caution in patients with heart failure.

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

Hepatic Impairment

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.

Laboratory Tests

There was a greater decrease in hemoglobin and hematocrit in the combination product compared to either component alone.

Adverse Reactions

The only adverse reaction that occurred in greater than or equal to 3% of patients treated with AZOR and more frequently than placebo was edema. The placebo-subtracted incidence was 5.7% (5/20 mg), 6.2% (5/40 mg), 13.3% (10/20 mg), and 11.2% (10/40 mg). The edema incidence for placebo was 12.3%.

Adverse reactions seen at lower rates but at about the same or greater incidence as in patients receiving placebo included hypotension, orthostatic hypotension, rash, pruritus, palpitation, urinary frequency, and nocturia.

In individual clinical trials of amlodipine and olmesartan medoxomil, other commonly reported adverse reactions included headache, dizziness, and flushing.

For more information on AZOR, call 877-4-DSPROD (877-437-7763) or go to the web site www.azor.com.

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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