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New Head-to-Head Hypertension Study Shows Benicar® Superior to Cozaar®

Patients treated with Benicar® in BeniVICTOR study experienced significantly greater blood pressure reductions and higher goal attainment rates than patients treated with Cozaar® after 8 weeks

Parsippany, NJ – October 1, 2010 – New study results show that patients treated with Benicar® (olmesartan medoxomil) 40 mg once daily had significantly greater reductions in blood pressure and higher rates of goal attainment than patients receiving Cozaar® (losartan potassium) 100 mg once daily at week 8, according to findings of a new head-to-head study presented today at the late breaker session at the 23rd Scientific Meeting of the International Society of Hypertension (ISH) in Vancouver, Canada. Benicar and Cozaar* are two of the leading angiotensin II receptor blockers (ARBs).[1] The study did not evaluate the Cozaar 50 mg BID (twice a day) dose.[2]

The BeniVICTOR study, **B**enicar **E**fficacy: **N**ew **I**n**V**estigation **I**n the **C**omparison of BP reductions be**T**ween **O**lmesartan and losa**R**tan in patients with hypertension, met its primary endpoint of mean change from baseline in Seated Diastolic Blood Pressure (SeDBP) at 8 weeks. At week 8, patients treated with Benicar 40 mg achieved reductions of 13.6 mm Hg Seated Systolic Blood Pressure (SeSBP) and 9.7 mm Hg SeDBP from a mean baseline blood pressure of 158.2/101.1 mm Hg. Patients treated with Cozaar 100 mg experienced a smaller mean blood pressure reduction of 9.7/7.1 mm Hg from a baseline of 158.3/101.3 mm Hg. The treatment difference between Benicar 40 mg versus Cozaar 100 mg was 3.9/2.5 mm Hg (P≤ 0.0001).[2]

Further, patients treated with Benicar reported significantly greater goal attainment when compared to patients treated with Cozaar. At week 8, a significantly greater proportion of patients treated with Benicar 40 mg achieved a blood pressure goal of <140/90 mm Hg than patients treated with Cozaar 100 mg (31.6 percent versus 19.5 percent, respectively; P<0.0001)".[2]

"Achieving blood pressure control is difficult for many patients so being able to identify which angiotensin II receptor blocker provides superior blood pressure reduction can be very important for physicians," said Dr. Henry Punzi of the Trinity Hypertension and Metabolic Research Institute in Carrollton, Texas. "Many patients come close to achieving goal, but are unable to cross the threshold of controlled blood pressure. For many patients, a reduction of two or three points in their blood pressure

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*Note: Cozaar (losartan) is marketed in the U.S. by Merck; losartan is also marketed generically by TEVA Pharmaceuticals USA, Lupin LTD, Zydus Pharmceuticals USA, Actavis US, Apotex, Upsher Smith Laboratories, Torrent Pharmaceuticals Ltd., Aurobindo Pharma and Roxane Laboratories Inc.

is the difference between being able to achieve control or remaining uncontrolled. The results of BeniVICTOR show that Benicar was more effective at reducing blood pressure than Cozaar, which could help bridge the gap for many patients."

High blood pressure can cause permanent changes to blood vessels and the heart that may create serious problems elsewhere in the body.[3] Hypertension is one of the most prevalent conditions in the United States, affecting approximately one in three American adults (about 74.5 million people aged 20 and older) and approximately one billion people worldwide.[4,5] High blood pressure is often difficult to control, and of those with high blood pressure, approximately 56 percent, do not reach recommended blood pressure levels.[4] The number of people with high blood pressure is expected to reach about 1.6 billion worldwide by 2025.[6]

Study Design

BeniVICTOR was an 8-week, prospective, double-blind, multicenter, forced-titration study evaluating the comparative safety and efficacy of Benicar and Cozaar in 941 patients with hypertension. Mean blood pressure was 158.3/101.2 mm Hg at baseline. Following a 3-4-week placebo run-in, patients were randomized to treatment with Benicar 20 mg, Cozaar 50 mg, or placebo once daily. At Week 2, placebo-treated patients were rolled into the Benicar 20 mg arm for the next 2 weeks. After 4 weeks, patients were titrated to Benicar 40 mg or Cozaar 100 mg once daily for 4 additional weeks. For the efficacy analysis, all patients that received Benicar were combined together into one group versus the Cozaar group.

The primary endpoint of the study was the mean change from baseline in SeDBP at week 8. The secondary endpoints included: mean change in SeSBP at week 8 and mean change in SeBP from baseline at week 4. Additionally, tertiary goals included: the proportion of subjects achieving SeBP goal at week 8 (<140/90 mm Hg).[2]

Treatment with both Benicar and Cozaar was well-tolerated, with the majority of adverse events (AEs) being mild-to-moderate in severity. The most commonly reported drug-related treatment emergent adverse events (TEAEs) were headache, reported by subjects in both the combined olmesartan group (1.9 percent) and the losartan group (2.8 percent), followed by dizziness (1.1 vs. 0.4 percent, respectively) and nausea (1.1 vs. 0.6 percent, respectively).

About Benicar®

Angiotensin II is a hormone that interacts with a receptor on arterial blood vessels, which results in constriction of the blood vessels and increased 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 effect of angiotensin II on the AT1 receptor on the blood vessels, which may lead to relaxation of the blood vessels and the inhibition of the release of the hormone which causes salt

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retention and increased blood volume.

Benicar is indicated for the treatment of hypertension in adults and pediatric patients 6 to 16 years of age, alone or with other antihypertensive agents. Benicar may be used as initial therapy.

IMPORTANT SAFETY INFORMATION ABOUT BENICAR®

WARNING – AVOID USE IN PREGNANCY
When pregnancy is detected, discontinue Benicar as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus [see Warnings and Precautions (5.1)].

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

Adverse Reactions

In adults:
● The withdrawal rates due to adverse reactions were similar with BENICAR to placebo: BENICAR (2.4% vs 2.7%)
● The incidence of adverse reactions with BENICAR was similar to placebo

— The only adverse reaction that occurred in >1% of patients treated with BENICAR and more frequently than placebo was dizziness (3% vs 1%)

— The adverse experience profile in pediatric patients were similar to those seen in adults

Dosage 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 treated with diuretics, particularly with impaired renal function), initiate BENICAR under close medical supervision and give consideration to use of a lower starting dose

*Creatinine clearance <40 mL/min.

Please see full prescribing information for BENICAR.

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About Daiichi Sankyo

The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

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[1] Data on file at DSI.
[2] BeniVICTOR Data Presentation: "Efficacy And Safety Of Olmesartan Medoxomil (OM) Compared With Losartan Potassium (LOS) In Patients With Hypertension (HTN)". Presented at ISH 2010.
[3] American Heart Association. High Blood Pressure: Why Should I Care. http://www.americanheart.org/presenter.jhtml?identifier=2129. Accessed April 22, 2010.
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[5] 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
[6] Kearney PM, et al. Global burden of hypertension: analysis of worldwide data. *Lancet* 2005, 365:217-23.