spotlight on health

FDA Grants Marketing Approval For New Hypertension Treatment

(NAPSA)—The U.S. Food and Drug Administration (FDA) recently granted marketing approval for a new treatment option for hypertension. Benicar™ (olmesartan medoxomil), now available, is the newest entry in the rapidly growing angiotensin II receptor blocker (ARB) class, and has been proven to effectively lower diastolic blood pressure (DBP) (the bottom number of a blood pressure reading, the lowest pressure in the blood vessels between heartbeats, when the heart is at rest) and systolic blood pressure (SBP) (the top number of a blood pressure reading, the maximum pressure in the blood vessels as the heart contracts and circulates blood) in patients who suffer from hypertension.

"…reducing blood pressure even by a couple of extra points…may be important in reducing patients' risks of strokes, heart attacks and kidney disease."

Also known as high blood pressure, hypertension is called the "silent killer" because it has no specific symptoms and increases the risk of cardiovascular and related diseases such as stroke, heart attack, heart and kidney failure. Today, an estimated 50 million Americans suffer from hypertension; more than 30 percent are unaware that they have high blood pressure and approximately three-quarters of those being treated are not reaching the recommended goal.

Studies have shown that Benicar 20 mg—the recommended starting dose—taken once a day resulted in significant blood pressure reduction, lowering SBP by an average of 15 millimeters of mercury (mm Hg) and DPB by an average of 12 mm Hg, compared to baseline. In these studies, patients taking placebo had average reductions in SBP of 5.6 mm Hg and DBP of 6.2 mm Hg.

Developed by Sankyo Pharma Inc., Benicar can be administered alone or in combination therapy with other antihypertensive agents.

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"There's a lot of interest in Benicar," said Dr. Michael Weber, professor of medicine and associate dean of research, State University of New York Downstate College of Medicine, Brooklyn, N.Y. "We know Benicar is very effective at reducing blood pressure. And reducing blood pressure, even by a couple of extra points as compared with several existing blood pressure medications, may be important in reducing patients' risks of strokes, heart attacks and kidney disease."

With hypertension, it is important to achieve optimal blood pressure control. The Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure, coordinated by the National Heart, Lung and Blood Institute, recommends a blood pressure goal of below 140/90.

Benicar demonstrated superior blood pressure lowering efficacy over ARB market leader Cozaar® (losartan potassium) in two multicenter, randomized, double-blind clinical trials. The first study, published in the September/October 2001 issue of the *Journal of Clinical Hypertension*, included a comparison of Benicar to Cozaar in the treatment of essential hypertension at starting doses. Benicar was found to be significantly more effective than Cozaar in reducing average SBP and DBP as measured by 24-hour ambulatory monitoring, the most sensitive and objective technique available.

In a second study, patients receiving up to 20 mg of Benicar once daily achieved a significantly greater reduction of average blood pressure than those taking up to 100 mg of Cozaar once daily. The results were achieved after 12 weeks of therapy.

Angiotensin II is a potent vasoconstrictor that increases blood pressure. Benicar works by blocking angiotensin II receptors in blood vessels, resulting in lower SBP and DPB.

"We're very enthusiastic about Benicar," said Dr. John Alexander, President, Sankyo Pharma Development Division. "Clinical trials clearly establish the efficacy and safety of Benicar and demonstrate that it offers healthcare providers who treat hypertensive patients a new, viable option for controlling high blood pressure."

In clinical trials, Benicar demonstrated a side-effect profile similar to placebo. The only side effect that occurred in more than one percent of patients treated with Benicar and at a higher incidence versus placebo was dizziness (three percent vs. one percent).

Benicar, like all members of the ARB class, is not recommended for pregnant women. When used in pregnancy during the second and third trimesters, ARBs can cause injury and even death to the developing fetus. When pregnancy is detected, Benicar should be discontinued as soon as possible.

Benicar also has a favorable drug-drug interaction profile. No significant drug interactions were reported in studies in which Benicar was co-administered with digoxin or warfarin. In addition, Benicar is not metabolized by the cytochrome P450 enzyme system, so interactions with drugs that inhibit, induce or are metabolized by that system are not expected. Benicar is convenient, since it can be taken with or without food.

For full product information on Benicar, call 1-877-4-SANKYO (1-877-472-6596) or visit www.Benicar.com.