



NEWS RELEASE

Embargoed for release July 17, 2005

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DRUG FOR HYPERTENSION SHOWS PROMISE AS FUTURE TREATMENT FOR HYPERTENSIVE AFRICAN AMERICANS

July 17, 2005. San Juan, Puerto Rico. The beta-blocker, nebivolol, may be just what the doctor orders to control high blood pressure, especially among African Americans.

According to research presented today at ISHIB2005, nebivolol was shown to be statistically significantly better than placebo in reducing systolic and diastolic blood pressure among African-American hypertensive patients in a multicenter, randomized, double-blind, placebo-controlled study. In addition, adverse events from the medication were similar to those found in the group taking placebo only.

To conduct the clinical trial, Elijah Saunders, MD and colleagues randomly assigned 300 mild-to-moderate hypertensives to receive nebivolol in varying doses (2.5, 5, 10, 20, or 40 mg) or placebo once daily for 12 weeks. Nebivolol demonstrated a dose response, with numerically greater reductions in blood pressure with increasing nebivolol doses, up to 20 mg once daily. Reductions in diastolic blood pressure ranged up to 8.9 mm Hg (compared with a 2.8 mm Hg reduction with placebo); reductions in systolic blood pressure ranged up to 7.6 mm Hg (compared with a 0.4 mm Hg reduction with placebo).

“Beta-blockers are under-utilized among African Americans due to the perception that this form of anti-hypertensive medication is not effective,” stated Dr. Saunders, study author, ISHIB co-founder, and professor of medicine at the University of Maryland School of Medicine. “This study shows that nebivolol lowered blood pressure in a dose-dependent manner and was well-tolerated,” he continued.

The study found no statistically significant differences in the incidence of adverse events between the nebivolol and placebo groups. The most commonly reported adverse events were: headache (5.6% vs 4.1%, respectively); dizziness (3.6% vs 0%, respectively); arthralgia (3.6% vs 2.0%, respectively); diarrhea (3.2% vs 2.0%, respectively); fatigue (2.8% vs 0%, respectively); nasopharyngitis (2.4% vs 0%, respectively); and urinary tract infections (2.4% vs 0%, respectively).

Nebivolol is currently under review by the Food and Drug Administration (FDA). The FDA issued an approvable letter for nebivolol in May 2005. The drug is in Phase IIIB clinical trials to further assess its efficacy in the treatment of hypertension.¹ The study presented at today’s ISHIB’s 20th annual scientific meeting adds to the body of scientific knowledge about nebivolol and supports increased utilization of this important class of anti-hypertensive agents.

Nebivolol action

Nebivolol is believed to work in two ways. As a drug in the beta-blocker group of medicines, the drug works by selectively blocking beta₁-receptors in the heart and other organs of the body. By

Antihypertensive Drug Promising for African Americans, page 2

blocking these receptors, the drug prevents the action of two chemicals found naturally in the body: noradrenaline and adrenaline. Sometimes these chemicals are known as “fight or flight” chemicals because they are responsible for controlling the body’s reaction to stress. With these receptors and chemicals blocked, the heart beats more slowly and with less force.

Secondly, nebivolol has been shown to have a modest vasodilator effect via enhanced release of nitric oxide,²⁻³ which means it can widen the blood vessels, contributing to the maintenance of arterial pressure levels within the normal range. The combination of these two actions, as a beta-blocker and a direct vasodilator, may help provide a drug therapy that is both effective and better tolerated by the hypertensive patient.

This study was supported by Mylan Laboratories, Inc.

These research findings were presented at ISHIB2005. The abstract was presented during the conference’s poster presentation session at 1:00 PM, Sunday, July 17, 2005. ISHIB2005, an annual gathering of healthcare professionals from around the world, is jointly sponsored by the nonprofit ISHIB and ASH (American Society on Hypertension) and is taking place at the Caribe Hilton Hotel in San Juan, Puerto Rico during July 15-18.

ISHIB is a unique professional medical membership organization devoted to improving health and life expectancy of ethnic populations. ISHIB was founded in Atlanta, Georgia, in 1986 to respond to the problem of high blood pressure among ethnic populations. Each year, its international interdisciplinary conference presents advancements in the treatment and prevention of diseases concomitant to hypertension. In addition to US conference locations, other sites for the conference have included Toronto, London, the US Virgin Islands, Kenya, Cameroon and Brazil.

References

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2. Zwieter P. Nebivolol and endothelium dysfunction in salt-sensitive Dahl rats. *J Hypertens.* 2002;20:357.
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