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ANTIHYPERTENSIVE MEDICATION FOUND EFFECTIVE IN BOTH AFRICAN AMERICANS AND NON-AFRICAN AMERICANS

June 24, 2006 – Atlanta, Georgia. With a wide variety of antihypertensive medications available for treating high blood pressure, the pharmacological treatment of hypertension with amlodipine/atorvastatin single-pill dose was found to achieve blood pressure and cholesterol-lowering goals for those with hypertension. Comparing results from both the CAPABLE and GEMINI clinical trials, researchers at today's ISHIB2006 presented new data that supports the efficacy of a fixed-dose therapy combining a calcium antagonist (amlodipine) and a statin (atorvastatin) for lowering high blood pressure and high cholesterol levels in hypertensive patients.

In their study, John M. Flack, MD, MPH and colleagues wanted to find out if there was a difference between how well blood pressure was controlled by amlodipine/atorvastatin single-pill therapy in African Americans compared to nonAfrican Americans participating in the CAPABLE and GEMINI clinical trials. The CAPABLE Study was designed to determine the clinical utility of a single-pill combination drug (amlodipine/atorvastatin) in simultaneously achieving blood pressure and lipid goals in a specific population.[1] It was conducted as a 20-week, open-label, comparative, multicenter trial enrolling only high-risk African Americans with dyslipidemia and hypertension. The GEMINI trial was a 14-week, open-label, noncomparative trial of the efficacy of the same single-pill combination drug in a patient population of both African Americans and nonAfrican Americans.[2] Only results from nonAfrican American patients of the GEMINI trial were used in this comparison.

Both trials had the same entry criteria and patients in each were given the amlodipine/atorvastatin single pill at different doses according to their health status. The single pill was added to existing antihyperensive and cholesterol-lowering medications or introduced as sole treatment. For those in the CAPABLE study, attainment of blood pressure goals was based on recommendations of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7)[3]; recommendations from an earlier version of these guidelines (JNC 6)[4] were used for GEMINI study participants. Attainment of cholesterol levels was based on criteria set by the Third Report of the National Cholesterol Education Program Expert Panel on Detection, evaluation, and Treatment of High Blood Cholesterol I Adults (Adult Treatment Panel III).[5]

In their comparisons, Flack et al found that, at endpoint, nearly half of American Americans (48.3%) and more than half of nonAfrican Americans (58.5%) reached both blood pressure and cholesterol goals after using the single-pill therapy compared to only .8% and .6% at goal levels at the beginning of the study. Although fewer African Americans than nonAfrican Americans achieved blood pressure and cholesterol-lowering goals, the single-pill therapy significantly increased the numbers of individuals reaching goal in both groups. (Table 1)

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Table 1. Study participants attaining blood pressure and cholesterol lowering goals

	African Americans achieving BP, LDL-C goals (%)		NonAfrican Americans achieving BP, LDL-C goals (%)	
	Week 20	Week 0	Week 20	Week 0
Overall BP and LDL-C	48.3	.8	58.5	.6
Blood pressure	56.8	1.4	66.0	2.2
LDL-C	73.7	28.5	82.7	38.9

BP=blood pressure; LDL-C=Low density lipoprotein cholesterol.

The development of these findings has provided "additional proof that the single-pill amlodipine/atorvastatin combination can effectively target modifiable risk factors for cardiovascular disease (high blood pressure and high cholesterol) in both populations," stated Dr. Flack. "Attaining the recommended goal levels in these high-risk populations can improve their chances for better heart health outcomes and lower the risk of further cardiovascular complications. This combination therapy appears to be effective and well tolerated for both groups," he added.

Dr. Flack is a professor of medicine and physiology, interim chair and chief, Division of Translational Research and Clinical Epidemiology, Department of Medicine, Wayne State University (WSU).

These scientific findings were presented today at the 21st International Interdisciplinary Conference on Hypertension and Related Cardiovascular Risk Factors in Ethnic Populations as Abstract 047. The abstract appears below.Additional conference information and news from the conference can be found at http://www.ishib.org/ISHIB2006.

1. Flack JM, Victor R, Watson K, et al. Amlodipine/atorvastatin single pill improves goal attainment in the treatment of hypertension and dyslipidemia in African Americans: The CAPABLE trial. Program and abstracts from the American Society of Hypertension 21st Annual Scientific Meeting: May 16-20, 2006; New York, NY.
2. Neutel J, LaSalle J, Berman L, et al. Dual goal attainment with amlodipine/atorvastatin single pill in a broad range of patients: results from the GEMINI study. *Am J Hypertens*. 2005;17(5 pt 2): 184A.
3. Chobanian AV, Bakris GL, Black HR, et al. Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. National Heart, Lung, and Blood Institute; National High Blood Pressure Education Program Coordinating Committee. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension.* 2003;42:1206-1252.
4. Sheps, SG, Black HR, Cohen JD, et al for the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Sixth Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.* National Institutes of Health, National Heart, Lung, and Blood Institute; National High Blood Pressure Education Program: Bethesda, MD. 1997.
5. National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III final report. *Circulation.* 2002;106:3143-3421.

ISHIB2006 is jointly sponsored by ISHIB and the American Society of Hypertension (ASH). ISHIB (The International Society on Hypertension in Blacks) is a nonprofit, professional medical membership organization devoted to improving the 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 cardiovascular diseases and reducing the health disparities among ethnic minority populations. In addition to US conference locations, other sites for the conference have included Toronto, London, the US Virgin Island, Kenya, Cameroon, and Brazil.

ISHIB2006 ABSTRACTS 047: Presented during Poster Presentation Sessions on June 24 and 25, 2006

A COMPARISON OF GOAL ATTAINMENT BETWEEN AFRICAN AMERICANS AND NON-AFRICAN AMERICANS TREATED WITH AMLODIPINE/ATORVASTATIN SINGLE-PILL THERAPY: A POST-HOC COMPARISON OF THE CAPABLE AND THE GEMINI TRIALS

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Objectives. To compare goal attainment in African Americans and non-African Americans treated with amlodipine/atorvastatin singe-pill therapy.

Methods. CAPABLE and Gemini were open-label, non-comparative, multicenter trials investigating the efficacy/safety of amlodipine besylate/atorvastatin calcium single pill in patients with concomitant hypertension and dyslipidemia. Both trials had the same entry criteria except that CAPABLE enrolled only African Americans whereas only non-African-American patients from Gemini (90.1% of the original study) were included in this analysis. Eight dosage strengths of amlodipine/atorvastatin single pill (5/10, 5/20, 5/40, 5/80, 10/10, 10/20, 10/40, 10/80 mg) were administered in both trials as initial, add-on, or substitution therapy and electively titrated to improve blood pressure (BP) and lipid control. The primary efficacy assessment was the percentage of patients attaining both BP (CAPABLE, JNC 7; Gemini, JNC 6) and low-density lipoprotein cholesterol (LDL-C; NCEP ATP III) therapeutic goals (for differences between these trials).

Results. At endpoint, 48.3% of African Americans vs 58.5% of non-African Americans reached both BP and LDL-C goals (vs 0.8% and 0.6% at baseline). 56.8% of African Americans vs 66.0% of non-African Americans reached BP goals (vs 1.4% and 2.2% at baseline). LDL-C goals were reached by 73.7% of African Americans vs 82.7% of non-African Americans (vs 28.5% and 38.9% at baseline).

Conclusions. Amlodipine/atorvastatin single pill improves attainment of BP/LDL-C goals in African Americans and non-African Americans. Goal attainment was lower in African Americans; a number of factors may have contributed to this.

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