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INDAPAMIDE SR-BASED TREATMENT IS BENEFICIAL IN REDUCING FATAL STROKES, CARDIOVASCULAR EVENTS AND ALL-CAUSE MORTALITY IN VERY ELDERLY HYPERTENSIVES

CHICAGO, IL – Results of research being presented today at the American College of Cardiology’s 57th Annual Scientific Session show that treatment of high blood pressure based on indapamide sustained release (SR) 1.5mg is beneficial in very elderly hypertensives in reducing fatal strokes and cardiovascular events as well as all-cause mortality.

The Hypertension in the Very Elderly (HYVET) Trial was a randomized double-blind placebo-controlled study involving patients aged 80 or older. The trial randomized 3,845 patients with a mean age at baseline of 84±3 years and a mean entry blood pressure of 173/91 ± 9/8 mmHg. Entry criteria included a systolic blood pressure of 160-199 mmHg. Active treatment was indapamide (SR) 1.5mg with the addition of perindopril 2-4 mg, in tablet form once a day as required, to reach a target blood pressure of 150/80 mmHg. The primary end-point was all-strokes.

“Before our study, doctors were unsure about whether very elderly people with high blood pressure could see the same benefits from treatment to lower their blood pressure as those we see in younger people,” said Emeritus Professor Christopher Bulpitt, the lead investigator on the study from the Care of the Elderly group at Imperial College London. “Our results clearly show that many patients aged 80 and over could benefit greatly from treatment. Populations are living longer and we have growing numbers of people living well into their 80s and beyond, so this is good news.”

While elevated blood pressure levels are common among very elderly hypertensive patients, the benefit-to-risk ratio for treating such patients had not been established to

date. Epidemiological data suggested decreased mortality with higher blood pressure levels. Intervention trials had not included sufficient numbers in the 80-plus age group to clarify this association.

The average follow-up for the HYVET study was just over two years, by which time 20 percent of the placebo subjects and 48 percent of those taking medication had achieved the target blood pressure of 150/80 mmHg. In patients followed longer, a greater number who received active treatment achieved the target blood pressure.

In July 2007, the HYVET steering committee accepted the recommendations of the independent trial data-monitoring and ethics committees to stop the trial early. This was based on the results from the second planned interim analysis that showed a significant reduction in the primary endpoint and total mortality.

The HYVET study final results showed a 21 percent ($p=0.02$) reduction in total mortality rate and a 30 percent reduction in the rate of all-strokes although the latter did not reach statistical significance ($p=0.06$). A significant reduction of 39 percent ($p=0.05$) was observed in the rates of fatal strokes, of 64 percent ($p<0.001$) in fatal and non-fatal heart failure, and 34 percent ($p<0.001$) in cardiovascular events. The benefits were apparent within the first year of follow-up.

“These results will have important implications for the generation of future guidelines and mean that very elderly individuals with sustained systolic blood pressures of 160 mmHg or more should now be appropriately assessed and treated in accordance with the new findings,” added Nigel S. Beckett, M.D., the trial coordinator from the Care of the Elderly group at Imperial College London.

Sponsored by Imperial College London, HYVET was the largest randomized, controlled trial assessing the benefit-to-risk ratio of treating hypertensive patients 80 years of age and older. The results showed that lowering blood pressure of elderly patients could cut their total mortality by a fifth and their rate of cardiovascular events by a third. The findings have the potential to affect the treatment and impact the health outcomes of millions of individuals.

The HYVET trial results will be simultaneously published in the *New England Journal of Medicine*.

Dr. Beckett will present this study, “The Hypertension in the Very Elderly Trial (HYVET): Main Results” on Monday, March 31 at 10:30 a.m. in North Hall B1.

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The American College of Cardiology (www.acc.org) represents the majority of board certified cardiovascular physicians in the United States. Its mission is to advocate for quality cardiovascular care through education, research, promotion, development and application of standards and guidelines- and to influence health care policy. ACC.08 is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.