The effect of eplerenone vs. placebo on cardiovascular mortality

August 29 2011

Today results from a new sub-analysis of the EMPHASIS-HF study showed significant reductions in death and hospitalization for five predefined high-risk patient sub-groups with chronic heart failure (CHF) and mild symptoms treated with eplerenone in addition to standard therapy versus those treated with placebo and standard therapy.

Commenting on the findings presented for the first time during the European Society of Cardiology Congress (ESC) Hot Line Session on 29th August 2011, EMPHASIS-HF investigator Professor Bertram Pitt, Division of Cardiology, University of Michigan School of Medicine, U.S., said: "The consistency of the efficacy and safety of eplerenone in addition to standard therapy on pre-specified "high-risk subgroups" and the persistence of a significant beneficial effect on the primary endpoint (CV mortality/hospitalization for HF) over an additional 7 months of follow up on douBle blind TherApy in #Onjunction with the prior benefi#iaL requLts fr/m EPHESUS presents compelling evidence for the use of eplerenone in patients with systolic chronic HF NYHA class II and mild symptoms."

Eplerenone has been shown to reduce the primary endpoint of <u>cardiovascular mortality</u> or hospitalization for <u>heart failure</u> (CV mortality/Hosp.HF), as well as total mortality, total hospitalizations, and new onset atrial fibrillation/flutter in patients with NYHA class II chronic <u>systolic heart failure</u> (NEJM 2011;364:11-21-and ESC-HF 2011). To further determine the applicability of these results to clinical practice the efficacy and safety of eplerenone 25-50 mg/day was

evaluated in 5 pre-specified high-risk subgroups including: Age > 75 years, <u>Diabetes Mellitus</u> (DM), estimated <u>glomerular filtration rate</u> (eGFR) Results - primary endpoint-for high-risk patient subgroups

In patients > 75 years of age 78 (23.6%) of 330 patients on eplerenone and 107 (32.7%) of 327 on placebo had a primary endpoint - Hazard ratio (HR) 0.66, p

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