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## IS THERE A ROLE FOR SERIAL OUTPATIENT DRUG INFUSIONS IN ADVANCED HEART FAILURE?

**NEW ORLEANS, La. (March 25, 2007)** — For patients with severe chronic heart failure, known as stage D or chronic decompensated heart failure (CDHF), hospitalization is frequent and treatment options are limited. The FUSION II trial (Follow-Up Serial Infusions of Nesiritide in Advanced Heart Failure) tested the benefit of a novel drug infusion regimen of serial administration of nesiritide (NES) versus placebo in outpatients with advanced heart failure and a primary endpoint of all cause mortality and cardiorenal hospitalizations. While the primary results were neutral, it is important to note that there was no evidence of renal harm or excess mortality attributed to use of nesiritide, according to this follow-up study presented today at the American College of Cardiology's 56<sup>th</sup> Annual Scientific Session. ACC.07 is the premier cardiovascular medical meeting, bringing together cardiologists and cardiovascular specialists to further breakthroughs in cardiovascular medicine.

NES, a recombinant form of human B-type natriuretic peptide, is approved in the United States for the treatment of acute decompensated heart failure (ADHF), but questions regarding the safety of nesiritide have been raised. Currently, it is primarily administered to hospitalized patients, but this research tested the potential benefit and safety of outpatient treatment to improve the natural history of CDHF.

FUSION II was a randomized, double-blind, placebo-controlled study conducted in 920 stage D CDHF patients. The trial was designed to prospectively evaluate efficacy and safety concerns of serial

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## *2 – 2 – 2 Results from FUSION II Trial*

outpatient NES infusions in stage D patients following promising signals from FUSION I. Patients in FUSION II were randomized to NES 2 mcg/kg bolus and 0.01 mcg/kg/min for 4-6 hours (n= 605) or matching placebo (n= 306) once or twice weekly for 12 weeks, with a 4-week taper and 8-week follow-up.

Background therapy was excellent with high compliance regarding standard, evidence-based medical and device therapy, along with an extraordinary program of precise disease management. The event rates in FUSION II were 33 percent lower than that seen in FUSION I, likely due to the excellent background therapy and medical care. Of note, outpatient inotropic (referring to an increase in the heart's beating strength) support was allowed in FUSION I, but not permitted in FUSION II. In that context, the primary effect of NES infusion therapy was neutral, as the benefit of background therapy was substantially greater than that seen in the first trial. Regarding the questions of safety that persist with the use of nesiritide, this study demonstrated no evidence of renal harm or excess mortality.

"This is the largest heart failure trial to date in patients with stage D heart failure, the least stable of all heart failure patients who are in dire need of novel treatment methods. Serial administration of outpatient nesiritide infusions was not shown to be significantly beneficial in the context of excellent care. The lesson learned here is that appropriate use of evidence-based medical and device therapy, as well as avoidance of non-evidence based therapies done in concert with highly sophisticated and rigorous follow-up, is beneficial even in advanced disease," said Clyde W. Yancy, M.D., of Baylor University Medical Center at Dallas, and lead study author. "Practitioners should follow the current guidelines and strive to achieve optimal medical and device therapy in this patient population. It is reassuring to note that the safety data regarding nesiritide, obtained in this vulnerable patient population who have advanced heart failure, are neutral and support ongoing further investigations of this novel compound."

*Dr. Yancy will present this study, "Results of the Follow-Up Serial Infusions of Nesiritide for the Management of Patients With Heart Failure (FUSION II) Trial," on Sunday, March 25 at 9:10 a.m. in Hall A.*

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The American College of Cardiology ([www.acc.org](http://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.07 and the i2 Summit is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in the treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.