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RELAXIN SHOWS PROMISING RESULTS IN ACUTE HEART FAILURE

Dose-Finding Study Reports Significant Symptom Relief, Other Key Improvements

Orlando, FL – A naturally occurring hormone that helps women adapt to the cardiovascular stresses of pregnancy is showing promise as a treatment for acute heart failure, rapidly helping patients to breathe more easily and improving other measures of heart failure severity and clinical outcomes, according to research presented today at the American College of Cardiology’s 58th annual scientific session. ACC.09 is the premier cardiovascular medical meeting, connecting cardiologists and cardiovascular specialists to the latest and most innovative findings in cardiovascular science.

The Pre-RELAX-AHF study found that, when given in addition to standard treatment, the hormone relaxin improved the hospital course of patients, prevented heart failure from worsening during hospitalization and shortened hospital stay. After discharge, longer-term benefits were observed as well. But what patients may have appreciated most, the hormone substantially relieved shortness of breath, or dyspnea, within just a few hours, an improvement that persisted over several days.

“Over 90 percent of patients with acute heart failure have dyspnea, and for the majority of these patients, it is the dyspnea that causes them to seek medical care,” said John R. Teerlink, M.D., professor of clinical medicine at the University of California San Francisco and director of the Heart Failure Clinic at the San Francisco Veterans Affairs Medical Center. “Consequently, improvement of dyspnea is an important and clinically relevant target of heart failure therapy.”

The problem of acute heart failure continues to grow. Over the last 10 years, hospitalization for heart failure has increased 25 percent, now accounting for some 1.1 million hospital stays each year in the United States and costing more than \$20 billion. Relaxin, which causes blood vessels to dilate, takes pressure off the heart, and increases blood flow to the kidneys, has the potential to overcome many of the body’s natural but harmful responses to impairment in the heart’s

pumping ability. These effects may be particularly beneficial in the approximately 60 percent to 80 percent of patients who initially have normal or high blood pressure, since constriction of blood vessels likely plays a central role in their acute heart failure.

The Pre-RELAX-AHF study was designed to evaluate the safety and best dose of intravenous relaxin in patients with acute heart failure and normal or elevated blood pressure. Researchers recruited a total of 234 patients from eight countries. All patients had shortness of breath even while resting and showed congestion on a chest x-ray. Patients were randomly assigned to receive a placebo or intravenous relaxin at doses of 10, 30, 100, or 250 mcg/kg/day for two days.

The 30-mcg/kg dose of relaxin (relaxin-30) turned out to be the most effective. More patients (41 percent) reported moderate or marked improvements in dyspnea at six, 12 and 24 hours when treated with relaxin-30, as compared to 23 percent of patients assigned to placebo ($p = 0.04$). Relief remained significantly greater in the relaxin-30 group at day 14. Researchers also noted trends toward greater fluid and weight loss, less need for intravenous diuretics, and less deterioration of heart failure in the hospital. When all of the doses of relaxin were compared with placebo, hospital stay was one to two days shorter, on average. The safety profile of relaxin in the study was favorable as well, Teerlink said.

After 60 days, 3 percent of patients in the relaxin-30 group had been hospitalized for heart failure or died of cardiovascular causes, as compared to 17 percent in the placebo group ($p = 0.06$), over an 80 percent reduction. During an average follow-up of 4.5 months, no patients in the relaxin-30 group died of cardiovascular causes, as compared with 14 percent of those in the placebo group ($p = 0.046$).

“Relaxin is a promising new therapy for acute heart failure that requires further testing in additional, larger clinical trials,” said Marco Metra, M.D., co-principal investigator and a professor of medicine at the University of Brescia, Brescia, Italy.

Dr. Teerlink will present the study “Relaxin, A Novel Treatment for Acute Heart Failure: The Results of the Pre-RELAX-AHF Study” on Sunday, March 29 at 11:21 a.m. in Hall A2.

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The American College of Cardiology (www.acc.org) works to influence health care policy and represents the majority of board certified cardiovascular care specialists through education, research, promotion, and the development and application of standards and guidelines. ACC.09 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.