



News Release

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Results From Study Show Promising Efficacy and Safety Results for Corthera's Relaxin in Acute Heart Failure

Data Presented at Late-Breaking Clinical Trials Session at ACC 58th Annual Scientific Session; Results Published On-Line in The Lancet

SAN MATEO, Calif., March 29, 2009 – Corthera Inc. today announced that results from PRELAX-AHF, the Phase II portion of a Phase II/III multicenter, randomized, double-blind, placebo-controlled international study, demonstrated promising efficacy and safety for relaxin, the company's investigational drug for treatment of acute heart failure (AHF). The report containing the detailed study results is being published on-line in the medical journal, *The Lancet*.

The data from 234 patients in eight countries showed that when administered with standard-of-care therapy for acute heart failure, relaxin caused rapid, substantial and sustained relief from dyspnea (breathlessness). Relaxin also demonstrated consistent trends in improvement of the hospital course of patients, prevention of heart failure worsening during hospitalization, shortening of in hospital stay and improved longer-term outcomes following discharge when compared to placebo. John R. Teerlink, M.D., professor of medicine, University of California San Francisco, Director of Heart Failure, Veterans Affairs Medical Center, San Francisco and co-principal investigator of the study, presented the findings today at a late-breaking clinical trials session at the American College of Cardiology's (ACC) 58th Annual Scientific Session in Orlando, Fla.

"The results of the study clearly indicated favorable treatment effects on symptoms, signs and outcomes in patients hospitalized with AHF," said Teerlink. "The use of relaxin led to considerable improvement in dyspnea when compared to placebo and lasted up to 14 days, longer than any therapy studied. In this study, relaxin administration was safe and well tolerated. These results provide a clear direction for the Phase III study."

Marco Metra, M.D., professor of cardiology at the University of Brescia, Italy, and co-principal investigator of the study, added: "There has been an epidemic of hospitalization for heart failure and there is a great need for an advance in the treatment of AHF. The potential benefits of relaxin shown by the Phase II study are extremely encouraging, and the larger Phase III study currently getting underway, RELAX-AHF-1, will aim to confirm relaxin's safety and efficacy in treating patients with AHF."

“We are very pleased to have our study results presented in this important forum at the ACC and published in the prestigious journal The Lancet. This represents international recognition of the important need for new therapies for AHF and the promise that relaxin holds for patients with AHF,” added Stan Abel, CEO of Corthera.

Corthera’s Pre-RELAX-AHF / RELAX-AHF study is a Phase II/III, multicenter, randomized, double-blind, placebo-controlled, parallel-group, international trial designed to evaluate the efficacy and safety of relaxin for the treatment of AHF. In the Phase II Pre-RELAX-AHF study, the objective was proof-of-concept and dose and endpoint selection. Patients selected for the study presented to the hospital with dyspnea due to AHF and with normal or elevated blood pressure. In the Phase III RELAX-AHF study, the objective is to confirm safety and efficacy. The Pre-RELAX-AHF / RELAX-AHF study was designed and conducted in collaboration with Momentum Research, headed by Dr. Gad Cotter, a noted heart failure expert.

Patients in the Pre-RELAX-AHF study were randomly assigned to receive intravenous relaxin at doses of 10, 30, 100, or 250 mcg/kg/day or placebo for two days. The study indicated that the 30-mcg/kg dose of relaxin (relaxin-30) was the most effective. More patients, approximately 40%, reported moderate or marked improvements in dyspnea at 6, 12 and 24 hours when treated with relaxin-30, as compared to 23% of patients assigned to placebo ($p=0.04$). Relief remained significantly greater at day 14. Researchers also noted trends with relaxin toward greater 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. Relaxin had a good safety profile in the study.

Following 60 days, 3% of patients in the relaxin-30 group had been rehospitalized for heart failure or died of cardiovascular causes, as compared to 17% in the placebo group ($p=0.06$), a greater than 80% reduction. After an average follow-up of four and a half months, no patients in the relaxin-30 group had died of cardiovascular causes, as compared to 14% of those in the placebo group ($p=0.046$).

According to US data, there are more than 3 million hospital discharges each year with heart failure as a diagnosis, with a significant short-term rehospitalization rate and one-year mortality rate. It is the single largest expense to Medicare accounting for a total of \$13 billion in hospitalization costs. The great majority of acute heart failure patients have fluid accumulation in the lungs (congestion) that causes shortness of breath and other complications. For these patients, the current standard of care includes diuretics and vasodilators. Available agents from both of these classes of agents have been associated with renal impairment, hypotension and adverse outcomes.

About Relaxin

Relaxin is a naturally occurring peptide hormone that acts as a systemic and renal vasodilator through multiple vascular control pathways. Elevated levels of relaxin modulate increases in renal and cardiac function that meet the increased hemodynamic demands of pregnancy. Consistent with this natural role of the hormone, pharmaceutically manufactured relaxin has been shown to have these effects in multiple human studies of men and non-pregnant women. Data from the Pre-RELAX-AHF study, as well as a pilot study in patients with heart failure, support the expectation that these effects may be beneficial in relieving the signs and symptoms of heart failure.

About Corthera

Corthera Inc. is a biopharmaceutical company committed to acquiring, developing and commercializing therapies for illnesses in the acute care setting. Corthera's lead product candidate, relaxin, is currently being evaluated in clinical trials for acute heart failure. The company has worldwide rights to develop and commercialize relaxin. For more information, visit www.corthera.com.

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