

## **EMBARGOED FOR RELEASE AT 6 A.M. CST ON NOV. 10**

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### **Interim Analysis of Top-Line Data From Phase II/III Study Shows Favorable Efficacy & Safety for Corthera's Relaxin in Acute Heart Failure**

**SAN MATEO, Calif., Nov. 10, 2008** – Corthera Inc. today announced that an interim analysis of top-line data from Pre-RELAX-AHF, the Phase II portion of a Phase II/III multicenter, randomized, double-blind, international study, showed favorable efficacy and safety for relaxin, the company's investigational drug for treatment of acute heart failure.

The interim Phase II results were presented by John R. Teerlink, M.D., Professor of Medicine, University of California San Francisco, in a satellite symposium at the American Heart Association's (AHA) Scientific Sessions 2008 in New Orleans. The data from the first 209 patients enrolled in the trial demonstrated beneficial trends in acute heart failure (AHF) signs, symptoms and outcomes with no evidence of renal toxicity. Relaxin appeared safe and well-tolerated over a wide dose range.

"The data indicate that relaxin is a very promising treatment for AHF," said Teerlink, co-principal investigator of the study. "Compared to placebo, relaxin's effect on the important endpoint of relieving dyspnea, breathlessness, was apparent within 6 hours after start of treatment. These initial effects lasted up to 14 days after treatment, something not previously seen with other therapies for AHF. Relaxin's safety profile in the study's patient population was benign during and following drug treatment, while blood pressure effects were predictable and manageable. There were also encouraging trends in other in-hospital endpoints, including weight-loss due to diuresis, incidence of worsening heart failure and length of hospital stay. The consistency of these improvements across multiple measures of outcomes is very encouraging."

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. In Phase III RELAX-AHF, the objective is to confirm safety and efficacy. Patients selected for the study presented to the hospital with dyspnea (breathlessness) due to AHF and with elevated blood pressure and renal dysfunction. The Pre-RELAX-AHF / RELAX-AHF study was designed and conducted in collaboration with Momentum Research, headed by Dr. Gad Cotter.

Marco Metra, M.D., professor of cardiology at the University of Brescia, Italy, and co-principal investigator of the Pre-RELAX-AHF study, was also a speaker at the symposium. "Patients with AHF remain a major clinical challenge with extremely high morbidity and mortality rates. Promising new agents such as relaxin are needed to treat these patients and improve their outcomes. The data from the Phase II study met the objectives of the proof-of-concept Pre-RELAX-AHF study, allowing the selection of the appropriate dose and endpoints for further

study. Progression to the Phase III portion of the study is now clearly warranted,” said Dr. Metra.

According to the AHA, heart failure is a costly syndrome contributing to more than three million hospitalizations each year in the U.S. The great majority of patients with acute heart failure have fluid accumulation in the lungs (congestion) that causes shortness of breath (dyspnea) and other complications. For these patients, the current standard of care includes diuretics and vasodilators. 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. 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 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. Corthera has worldwide rights to develop and commercialize relaxin.

### **About Momentum Research**

Momentum Research, Inc. is a consulting and management organization with clinical expertise and leadership dedicated to the development of cardiovascular products and studies. For more information go to [www.momentum-research.com](http://www.momentum-research.com)

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