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## **Corthera's Relaxin Receives FDA Fast Track Designation for the Treatment of Acute Heart Failure**

**SAN MATEO, Calif., October 1, 2009** – Corthera Inc. today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to relaxin, the company's investigational drug for the treatment of acute heart failure (AHF). The Fast Track program facilitates the development and expedites the review of new drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

"Fast Track designation for the relaxin heart failure program is an important acknowledgement by the FDA of the need for advancements in the treatment of AHF," said Stan Abel, CEO of Corthera. "We are excited to be launching Phase 3 given our goal of advancing the development of relaxin as rapidly as possible for the benefit of patients who are in need of new treatment options."

Corthera's completed Pre-RELAX-AHF study is the Phase 2 portion of a Phase 2/3, 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 Pre-RELAX-AHF, the objective was proof-of-concept and dose and endpoint selection. Data from the Phase 2 study were presented at the American College of Cardiology conference earlier this year and published in the medical journal, *The Lancet*. These data from 234 patients in eight countries showed that when administered with standard-of-care therapy for AHF, patients receiving relaxin had greater and longer-lasting relief of dyspnea (shortness of breath). Relaxin treatment was associated with 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. Corthera is currently initiating enrollment in the Phase 3 RELAX-AHF study, the objective of which is to confirm the promising safety and efficacy of relaxin seen in these patients. 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 with acute heart failure remain a major clinical challenge with very high morbidity and mortality rates and limited treatment options" said 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 studies. "The importance of this Fast Track designation is two-fold as it acknowledges a significant unmet medical need and recognizes relaxin's potential as an important treatment option for patients with AHF."

According to U.S. data, there are more than 3 million hospital discharges each year with heart failure as a diagnosis, with significant short-term rehospitalization and one-year mortality rates. It is the single largest expense to Medicare, accounting for more than \$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 (dyspnea) 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. 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, including patients with heart failure.

#### **About Corthera**

Corthera Inc. is a private 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 the treatment of acute heart failure. The company has worldwide rights to develop and commercialize relaxin. For more information, visit [www.corthera.com](http://www.corthera.com).

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