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Results and Additional Analyses From Study Show That Corthera's Relaxin for Acute Heart Failure is the Strongest Predictor of Improved Longer-Term Outcomes Following Hospital Discharge When Compared to Other Variables

Data from Phase II/III Study Presented at Heart Failure Congress 2009 Demonstrate Promising Safety and Efficacy Results for Relaxin

SAN MATEO, Calif., June 1, 2009 – Corthera Inc. today announced that the results and additional statistical analyses conducted from Pre-RELAX-AHF, the Phase II portion of a Phase II/III multicenter, randomized, double-blind, international study, showed that relaxin, the company's investigational drug for the treatment of acute heart failure (AHF), was the strongest independent predictor of improved longer-term outcomes following hospital discharge when compared to other variables.

The new analyses of predictors of 60-day and 180-day outcomes, which included univariate and multivariate regression analyses, were presented today by Marco Metra, M.D., professor of cardiology at the University of Brescia, Italy, and co-principal investigator of the Pre-RELAX-AHF study, during a late-breaking clinical trials session at the annual meeting of the Heart Failure Association of the European Society of Cardiology (HFA-ESC 2009) in Nice, France.

Several variables, including baseline patient characteristics, early improvement in dyspnea (breathlessness) to day five, physician-determined occurrence of worsening of heart failure (WHF) during hospitalization, increased serum creatinine during hospitalization and relaxin administration, were included in the model to determine the important predictors of the two outcome measures: 60-day cardiovascular (CV) death or re-admission for heart failure and 180-day CV death. In the 60-day multivariate analysis, relaxin treatment was the strongest predictor of less CV death or heart failure re-admission ($p < 0.01$). Blood urea nitrogen (BUN) on admission ($p = 0.02$) and WHF during hospitalization ($p = 0.02$) were also significant predictors. Relaxin treatment was the only significant variable ($p < 0.01$) in both the multivariate and univariate analyses predicting CV death at 180 days.

"These new analyses, when added to the main results of Pre-RELAX-AHF, provide further indications that relaxin may be an important new therapy for patients admitted to hospital with acute heart failure," said Dr. Metra.

Five peer-reviewed posters with data and analyses from Pre-RELAX-AHF were also presented today. The insights from these analyses provided further evidence on the types of patients who

might benefit from therapy with relaxin, as well as the mechanisms by which relaxin causes these clinical benefits.

“There is a clear and urgent need for improved therapies for patients with acute heart failure,” said Piotr Ponikowski, M.D., Ph.D, head of the department of cardiology at the Clinical Military Hospital in Wroclaw, Poland, a principal investigator of the Pre-RELAX-AHF study and president-elect of the Heart Failure Association of the European Society of Cardiology. “We are encouraged by the preliminary results of the Pre-RELAX-AHF study, and we look forward to confirming them in the larger Phase III study, RELAX-AHF-1.”

Stan Abel, CEO of Corthera, added, “Acute heart failure is a global medical problem. The recognition of this problem by the international cardiology community underscores the important need for new therapies and the promise that relaxin holds for patients.”

Dr. Metra also presented the main results from Pre-RELAX-AHF for the first time in Europe on May 31 at the Judges’ Choice oral abstracts session at HFA-ESC 2009. These results were previously presented at the American College of Cardiology’s (ACC) 58th Annual Scientific Session and published in the *Lancet*. The data from 234 patients in eight countries showed that when relaxin was 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.

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 six, 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 worsening 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 and no patients 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 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.

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