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Novartis to acquire Corthera Inc., gaining worldwide rights to Phase III project relaxin for treatment of acute decompensated heart failure

- *Phase II results show relaxin has vasodilator (widens blood vessels) effects, improves breathlessness, reduces cardiovascular morbidity and days in hospital*
- *Acute decompensated heart failure (ADHF) remains a major clinical challenge with a high and increasing incidence and substantial morbidity and mortality*
- *Novartis to pay USD 120 million for acquisition; Corthera's current shareholders eligible for additional payments of up to USD 500 million contingent upon successful development and commercialization milestones*

Basel, December 23, 2009 - Novartis will gain exclusive worldwide rights to relaxin, a recombinant version of a naturally occurring human peptide, through the acquisition of the privately held US biopharmaceutical company Corthera Inc. Relaxin is currently in Phase III clinical trials as a potential treatment option for patients with acute decompensated heart failure (ADHF).

Novartis will assume full responsibility for the development and commercialization of relaxin, with regulatory submissions in the US and Europe planned for 2013. The US Food and Drug Administration (FDA) has granted "Fast Track" designation to relaxin as part of its program to expedite the review of new drugs intended to treat serious or life-threatening conditions that can potentially address unmet medical needs.

Relaxin, which is administered to hospitalized patients via a 48-hour infusion, has been shown to cause an increase in cardiac output, systemic and renal vasodilation, which suggests potential benefits for patients with ADHF. In its natural form, this peptide is responsible for relaxing the female reproductive tract as well as mediating the cardiovascular and renal changes during pregnancy, leading to studies showing its potential applications in this cardiovascular disease.

"Despite a range of current treatment options, acute decompensated heart failure is the leading cause of hospitalization in people over age 65 and remains a major clinical challenge with a high and increasing incidence and substantial morbidity and mortality," said Trevor Mundel, MD,

Global Head of Development at Novartis AG. “Relaxin will be an important addition to our expanding pipeline of novel development projects targeting cardiovascular disease.”

Acute decompensated heart failure – estimated to affect millions of people in the US and in Europe – is a condition often associated with chronic heart disease where patients typically suffer from severe shortness of breath (dyspnea) and the heart’s ability to pump blood from the lungs is impaired. As a result, the lungs become overfilled with fluid, which reduces oxygen uptake. Diuretics and vasodilators are the current standard of care, but available agents from these classes have been associated with renal impairment, low blood pressure (hypotension) and adverse outcomes.

“We are extremely pleased to be entering into this transaction with Novartis, given their world-class capabilities and global leadership position in cardiovascular disease,” said Stan Abel, President and Chief Executive Officer of Corthera. “This transaction highlights relaxin’s potential as an important treatment option for patients suffering from acute heart failure.”

Relaxin is expected to further strengthen the position of Novartis and its extensive range of cardiovascular medicines and development portfolio:

- **Diovan (valsartan)** – an angiotensin receptor blocker (ARB), is the number one selling hypertension medication worldwide[1], and is indicated in chronic heart failure (NHYA class II – IV). Diovan has been shown to significantly reduce hospitalizations for heart failure.[2]
- **Tekturna/Rasilez (aliskiren)** – a first-in-class direct renin inhibitor approved for treatment of hypertension that is also currently in Phase III studies for use in chronic heart failure.
- **LCZ696** – a single molecule dual-acting angiotensin receptor blocker / neprilysin inhibitor (ARNI) that entered Phase III development in late 2009 for systolic heart failure.
- **LCI699** – a Phase II and first-in-class aldosterone synthase inhibitor (ASI) being explored as a potential treatment for heart failure.

Relaxin also further complements the Novartis strategy to expand in acute cardiology care that includes elinogrel, an anti-platelet agent in Phase II development with potential to reduce the risk of heart attack and stroke. Novartis has hospital-based specialty sales forces in place to maximize the commercial potential of this development portfolio.

Corthera successfully completed Phase II clinical trials in early 2009 before initiating Phase III trials in October. Pre-RELAX-AHF, a 234-patient Phase IIb, placebo-controlled clinical trial, explored the efficacy, tolerability and safety of intravenous relaxin in patients with ADHF who had normal to severe high blood pressure.[3]

Terms of Agreement

Under the terms of the transaction, Novartis will acquire all of the outstanding shares of Corthera's stock for USD 120 million. In addition, Corthera's current shareholders will be eligible to receive additional payments of up to USD 500 million that are contingent upon clinical milestones, regulatory approval of relaxin and the achievement of commercialization targets. This transaction, which is subject to customary regulatory approvals, is expected to be completed in the first quarter of 2010.

Corthera Inc. is a private biopharmaceutical company. Corthera's investors include Domain Associates, Kleiner Perkins Caufield & Byers, Caxton Advantage Life Science Fund, and Sears Capital Management Inc.

* Novartis will acquire the exclusive worldwide rights for relaxin in all countries except Australia and Canada

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risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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References

[1] IMS Midas Worldwide Sales Data, May 2009

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