



## The Journal *Diabetes* Publishes Pre-clinical Data on Cortendo's Novel Diabetes Treatment, BP-2001

January 28, 2015 -- Göteborg, Sweden and Radnor, Penn., USA – [Cortendo AB](#) [ticker: CORT on NOTC-A], a global biopharmaceutical company focused on orphan endocrine disorders, is pleased to announce that the journal [Diabetes](#) published a scientific paper reporting on a pre-clinical study that details the glucose-lowering effect of BP-2001, an orally administered genetically modified probiotic being studied for the treatment of type 1 and type 2 diabetes.

“The pre-clinical data show that BP-2001 demonstrated the ability to reprogram intestinal endocrine cells into glucose-responsive insulin-secreting cells without affecting the normal function of nearby cells,” said Matthew Pauls, President and CEO of Cortendo. “These results provide evidence that BP-2001 has the potential to be a safe and effective oral treatment for diabetes, and we plan to submit an investigational new drug (IND) application with the FDA later this year.”

BioPancreate Inc., a wholly-owned subsidiary of Cortendo, has an exclusive license to this technology platform from Cornell University.

The paper entitled, “Engineered Commensal Bacteria Reprogram Intestinal Cells Into Glucose-Responsive Insulin-Secreting Cells for the Treatment of Diabetes,” was published online ahead of print in [Diabetes](#), the peer-reviewed scientific journal of the American Diabetes Association. The lead author of the paper is John C. March, PhD, an associate professor in the Department of Biological and Environmental Engineering at Cornell University in Ithaca, New York. The study was funded by the National Institutes of Health, the Hartwell Foundation and a NIH STTR grant with BioPancreate.

Cortendo is initially focused on developing and commercializing innovative products for orphan endocrine diseases, led by COR-003 (levoketoconazole), which is in Phase 3 development for endogenous Cushing’s syndrome. The company is exploring opportunities to work with potential partners to expand its orphan disease portfolio. The company also is exploring opportunities to out-license BP-2001.

### **About Cortendo AB**

Cortendo AB is a global biopharmaceutical company incorporated in Sweden and based in the United States. The Company’s initial strategic focus is to be the global leader in commercializing innovative medicines for orphan endocrine disorders. Cortendo is leading the way in the field of cortisol inhibition through the investigational drug, COR-003 (levoketoconazole) currently being studied in the Phase 3 global SONICS trial for the treatment of endogenous Cushing’s syndrome. COR-003 (levoketoconazole) has received orphan designation from both the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA). The Company’s intent is to independently commercialize its Orphan/Endocrine assets in key global markets.

### **About BioPancreate Inc.**

BioPancreate Inc. is a wholly-owned U.S. subsidiary of Cortendo AB. It is developing novel, orally administered biological therapeutics to treat endocrine disorders utilizing modified probiotic human bacteria. BioPancreate's lead product candidates for diabetes are modifications of naturally occurring bacteria that exist in the human gastrointestinal tract. Typically, natural probiotics have been shown to be both safe and beneficial when taken orally. The BioPancreate drug candidates deliver a human biological peptide directly into the gastrointestinal tract, triggering the transformation of intestinal enteroendocrine cells into glucose-responsive insulin-secreting cells, i.e. pancreas-like beta cells.

### **Risk and Uncertainty**

The development of pharmaceuticals carries significant risk. Failure may occur at any stage during development and commercialization due to safety or clinical efficacy issues. Delays may occur due to requirements from regulatory authorities, difficulties in recruiting patients into clinical trials due to physician or patient preferences or competing products, not anticipated by the company. There is no assurance that Cortendo will receive marketing and regulatory approvals necessary to commercialize or produce COR-003 (levoketoconazole) or other products. Regulatory approvals may be denied, delayed, limited or revoked.

The commercial success of COR-003 (levoketoconazole), if approved in a territory, cannot be predicted with certainty. In addition, Cortendo may face the risk of interrupted supply of COR-003 for clinical or commercial use from the subcontractors Cortendo has contracted.

### **Cortendo Forward-Looking Statements**

*This press release contains forward-looking statements concerning Cortendo that involve a number of risks and uncertainties. All statements other than statements of historical facts included in this press release, including, without limitation, statements regarding the Company's future financial position, strategy, anticipated investments, costs and results, plans, projects to enhance efficiency, outcomes of products development, future capital expenditures, liquidity requirements and objectives of management for future operations, may be deemed to be forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements or industry results to be materially different from those contemplated, projected, forecasted, estimated or budgeted, whether expressed or implied, by these forward-looking statements. Given these risks and uncertainties, investors should not place any undue reliance on forward-looking statements as a prediction of actual results. None of these forward-looking statements constitutes a guarantee of the future occurrence of such facts and data or of actual results. These statements are based on data, assumptions and estimates that the Company believes are reasonable. The forward-looking statements contained in this document are made only as of the date hereof. The Company expressly disclaims any obligation or undertaking to release publicly any updates of any forward-looking statements contained in this press release to reflect any change in its actual results, assumptions, expectations or any change in events, factors, conditions or circumstances on which any forward-looking statement contained in this press release is based.*

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