



For Release

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First Patient Successfully Implanted in Safety/Efficacy Study  
of Beta-O2's  $\beta$ Air Bio-Artificial Pancreas for Type 1 Diabetes

Uppsala University Hospital in Sweden will enroll 8 patients  
in the study, partially supported by a recent grant by the JDRF

Rosh Haayin, Israel, October 21, 2014 --- Beta-O2 announced today that the first patient participating in the company's first broad study of the  $\beta$ Air Bio-Artificial Pancreas has been successfully implanted.  $\beta$ Air is in development as a treatment and a potential cure for type 1 diabetes (T1D). Approximately 3 million people have T1D in the U.S.

Eight participants who meet [the study criteria](#) will be enrolled in the trial at Uppsala University Hospital in Sweden. Last month, JDRF awarded Beta-O2 a grant to fund half of the \$1M, two-year, open label, pilot investigation which will evaluate the safety and efficacy of implanting the  $\beta$ Air macro-encapsulation with human islets of Langerhans.

"The implant procedure took less than an hour. The patient remained hospitalized for four days thereafter for observation and was then discharged. Until day 180 following implantation, the patient will, among other protocol duties, be required to return to the clinic for monthly check-ups. On day 181,  $\beta$ Air will be explanted from the patient, who will continue to be followed for another 180 days," said Dr. Per-Ola Carlsson, principal investigator of the  $\beta$ Air study, professor at the Department of Medical Cell Biology, and the Department of Medical Sciences, Uppsala University. "We look forward to the results of this study and to possibly discovering a new and effective treatment for type 1 diabetes."

$\beta$ Air is composed of an immune protection unit, 68 mm in diameter and 18 mm wide, connected to two ports, also implanted under the skin, just under and to the right of the naval. The encapsulation contains islets of Langerhans, with its main constituent the beta-cells, which provide the insulin production in the body. Insulin is a hormone that is needed to transport sugar into cells, and thereby provide energy needed for daily life. The essential problem in T1D is that the body loses the insulin-producing beta-cells. Patients are to inject oxygen, once daily, into one of the two ports connected to the implant. This is done using  $\beta$ Air's oxygenation system

which automatically measures and calculates the required amount of oxygen. Oxygen is essential for the survival of the enclosed beta-cells as well as their ability to sense and produce the necessary quantity of insulin.

“We’re excited about the start of this clinical evaluation of the Beta-O2 encapsulation technology,” said Dr. Albert Hwa, JDRF Director of Discovery Research. “Encapsulated cell replacement therapies have the potential to transform the management of type 1 diabetes, so encapsulation research is a high priority for JDRF. We partnered with Beta-O2 to help speed this critical human study so we look forward to its rapid full enrollment and the study results as key next milestones.”

“The transplantation of cells in the  $\beta$ Air device does not require administration of immunosuppressive drugs and this is a significant advantage for patients,” said Dr. Olle Korsgren, Professor of Cell Therapy at the Department of Immunology, Genetics and Pathology at Uppsala University.

Dr. Dan Gelvan, chairman of the board of Beta-O2 and managing director of life sciences at Aurum Ventures said, “In the search for the holy grail of bio-artificial pancreases, there have always been three major obstacles: creating an implant that the body won’t reject so that the patient doesn’t need to take immunosuppressive drugs for the rest of their lives; finding a way to actively and regularly provide the correct amount of oxygen to the cells in the device in order to keep them happy, properly functioning and producing sufficient quantities of insulin; and finally, having enough cells in the device in the first place to generate as much insulin as the body needs at any given time. A normal pancreas has 1 million islets; 400,000 islets, however, are enough to get the job done. We believe we have created a healthy environment that will enable this many islets to live and function at an optimal level for an extended period of time.”

Dr. Gelvan continued, “We gained a great deal of confidence from the first in man study in 2013. Results demonstrated safety and the patient didn’t take any immunosuppression drugs while implanted. Protocol then, however, called for using 160,000 cells, rather than the preferred 400,000. So, although the patient never became completely insulin-free; he did, however, need considerably less. We hope that in the current study, transplanting a large enough amount of cells, combined with the  $\beta$ Air oxygenation system, will completely eliminate the need for insulin injections while the patients remain with the implant.”

#### **About Beta-O2 Technologies Ltd.**

Beta-O2 Technologies Ltd. is a biomedical company developing a proprietary implantable bioreactor, the  $\beta$ Air, for the treatment and potential cure of type 1 diabetes (T1D).  $\beta$ Air is designed to address the main problems of the otherwise successful procedures in which islets of Langerhans (i.e. pancreatic endocrine cells) are transplanted in diabetic patients, such as the need for life-long immunosuppressive pharmacological treatment and limited functionality of the transplanted islets over time due to an insufficient oxygen supply. Beta-O2 investors include SCP Vitalife Partners, Aurum Ventures, Pitango Venture Capital and Saints Capital. For more information, please visit [www.beta-o2.com](http://www.beta-o2.com).

#### **About Uppsala University Hospital**

Uppsala University Hospital is a referral hospital for more than 2 million inhabitants in Sweden. Its Center of Excellence in T1D is today one of the world-leading centers for interventional treatments in T1D, and includes the human islet isolation center for the Nordic countries. Regulatory approval for an investigator-driven  $\beta$ Air trial has been obtained from the Swedish authorities, and study participants are currently recruited for the trial. For more information, please visit [www.akademiska.se/en/CoE/Typ1Diabetes](http://www.akademiska.se/en/CoE/Typ1Diabetes) and <http://nordicislets.medscinet.com>

### **About JDRF**

JDRF is the leading global organization focused on type 1 diabetes (T1D) research. JDRF's goal is to progressively remove the impact of T1D from people's lives until we achieve a world without T1D. JDRF collaborates with a wide spectrum of partners and is the only organization with the scientific resources, regulatory influence and a working plan to bring life-changing therapies from the lab to the community. As the largest charitable supporter of T1D research, JDRF is currently sponsoring \$568 million in charitable research in 17 countries. For more information, please visit <http://jdrf.org/>

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