

Kadimastem and iTolerance's Proposed Collaboration Further Strengthened With Receipt of US \$1 Million BIRD Foundation Grant



The grant will support the preclinical and clinical development leading toward commercialization of iTOL-102, a potential cure for diabetes that does not require chronic immune system suppression

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The **Kadimastem** (TASE: KDST) and **iTolerance Inc.**'s proposed collaboration to develop a potential cure for diabetes was further strengthened today with the approval of NIS 3.5 million (US\$1 million) budget grant by Israel-U.S. Binational Industrial R&D Foundation (BIRD) to support their joint project to develop and commercialize a breakthrough regenerative technology to cure diabetes without the need for chronic immuno-suppression. The project will receive 3.5 million NIS (US \$1Million) grant from BIRD that will cover half of the proposed project budget and will be allocated over a period of 30 months.

 From left to right: Dr. Arik Hasson, Prof. Michel Revel, Anthony Japour, M.D., Mr. Asaf Shiloni, Dr. Kfir Molakandov

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This project is based on Kadimastem's diabetes product called **IsletRx**, which is comprised of clinical-grade clusters of human pancreatic islet like cells (ILCs). Preclinical studies have shown that the cells are able to detect the sugar levels in the body and to produce, and secrete glucose dependently, the required amounts of insulin and glucagon, just like a healthy pancreas and enables the insulin dependent patient to avoid an abnormal drop in sugar level (hypoglycemia).

In addition, the method of production and selection of the cells enables their implantation in various types of smaller size devices, suitable for maximum comfort for people living with diabetes. A key challenge, however, is possible immune rejection of the ILCs by the patient's body.

iTolerance, headquartered in Miami, Florida, has developed an innovative platform **technology (iTOL-100)** intended to enable the transplantation of allogeneic cells without tissue matching and without the need for chronic treatments that suppress the immune system of the transplant recipient (immunosuppression).

This platform technology was successfully demonstrated in preclinical experiments in large animals (non-human primates), where diabetes was cured by allogeneic transplantation, without the need for long-term immunosuppressive treatments.

The funding will be used to support the joint project that combines the aforementioned technologies towards clinical application of iTOL-102, an allogeneic cell product that can be transplanted without the need for chronic immunosuppressive treatments.

Kadimastem CEO Asaf Shiloni said, "We are exploring various ways with different partners to develop our stem cell-based treatments to cure diabetes. We would like to thank the BIRD Foundation for its support for our program with iTolerance. This milestone will enable us to move at a quicker pace, with the goal of starting the clinical trials of iTOL-102 within the 30-month grant period and ultimately to bringing to market in the U.S, Israel and worldwide, a cure for diabetes."

To the best of Kadimastem's knowledge, BIRD is considered one of the leading funds in its expertise in all branches of technology. During its 39 years of activity, the foundation has invested more than \$300 million dollars in projects that generated direct and indirect sales in the amount of more than \$10 billion dollars.

The BIRD Foundation's support for the Kadimastem-iTolerance project is an expression of high confidence in the unique technologies of the companies. It is also an important recognition of the ongoing dialogue between the two. BIRD supports approximately 20

projects annually with the goal of stimulating, promoting and supporting industrial R&D of mutual benefit to the U.S. and Israel. All approved projects have a company headquartered in Israel, with the partner company based in the United States.

Kadimastem Chairman of the Board Ronen Twito said, “The BIRD grant is good news all around. Kadimastem can now continue its important journey to develop a cure for diabetes. Those with diabetes can trust that indeed a cure is on the way. And a win for Kadimastem and the patients it serves means a big win for Kadimastem’s shareholders. Yes, good news all around.”

Kadimastem Chief Scientist, Professor Michel Revel said, “We always knew that cell therapy had high potential to provide a cure for diabetes. It is with great expectations that we watch this process unfold. Many thanks to the BIRD Foundation for helping to make it possible.”

About Kadimastem

Kadimastem is a clinical stage cell therapy company, developing and manufacturing "off-the-shelf", allogeneic, proprietary cell products based on its technology platform for the expansion and differentiation of Human Embryonic Stem Cells (hESCs) into functional cells. AstroRx®, the company's lead product, is an astrocyte cell therapy in clinical development for the treatment for ALS and in pre-clinical studies for other neurodegenerative indications.

IsletRx is the company's treatment for diabetes. IsletRx is comprised of functional, insulin and glucagon producing and releasing pancreatic islet cells, intended to treat and potentially cure patients with insulin-dependent diabetes.

Kadimastem was founded by Professor Michel Revel, CSO of the company and Professor Emeritus of Molecular Genetics at the Weizmann Institute of Science. Professor Revel received the Israel Prize for the invention and development of Rebif®, a multiple sclerosis blockbuster drug sold worldwide. Kadimastem is traded on the Tel Aviv Stock Exchange (TASE: KDST).

About iTolerance, Inc.

iTolerance is an early-stage privately held regenerative medicine company developing technologies to enable tissue, organoid or cell therapy without the need for life-long immunosuppression. Leveraging its proprietary biotechnology-derived Streptavidin-FasL fusion protein/biotin-PEG microgel (SA-FasL microgel) platform technology, iTOL-100, iTolerance is advancing a pipeline of programs using both allogenic pancreatic islets and stem cells that have the potential to cure diseases. The company’s lead program, iTOL-101 is being developed for Type 1 Diabetes and in a pre-clinical non-human primate

study, pancreatic islet cells co-implanted with iTOL-101 exhibited long-term function with control of blood glucose levels and restoration of insulin secretion without the use of chronic immune suppression. The company's second lead candidate, iTOL-102, is leveraging significant advancements in stem cells to derive pancreatic islets which allows an inexhaustible supply of insulin-producing cells. Utilizing iTOL-100 to induce local immune tolerance, iTOL-102 has the potential to be a cure for Type 1 Diabetes without the need for life-long immunosuppression. Additionally, the company is developing iTOL-201 for liver failure and iTOL-301 as a potential regenerative protein and cell therapy that leverages stem cell sources to produce proteins or hormones in the body in conditions of high unmet need without the need for life-long immunosuppression. For more information, please visit **[itolerance.com](https://www.itolerance.com)**.

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