Spin-off of the VUB Diabetes Research Center (DRC).

Established in 1998.

Milestones

- **1998:** Company incorporation.
- **2000:** BetaPREP™: isolation of the optimal, standardized mix of young piglet beta-cells and other endocrine cells, which adapt themselves to their host and produce Insulin-on-Demand™. Patent, now granted.
- **2009:** BetaGRAFT, a novel cell replacement therapy for type I diabetic patients.
- **2011:** BetaSCREEN, platform for drug screening in diabetes.
- **2012:** Pre-clinical development program.

BETA-CELL NV

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Over 50.000 insulin injections life-long (left) - 1 to 3 injections of insulin-producing beta-cells (right).

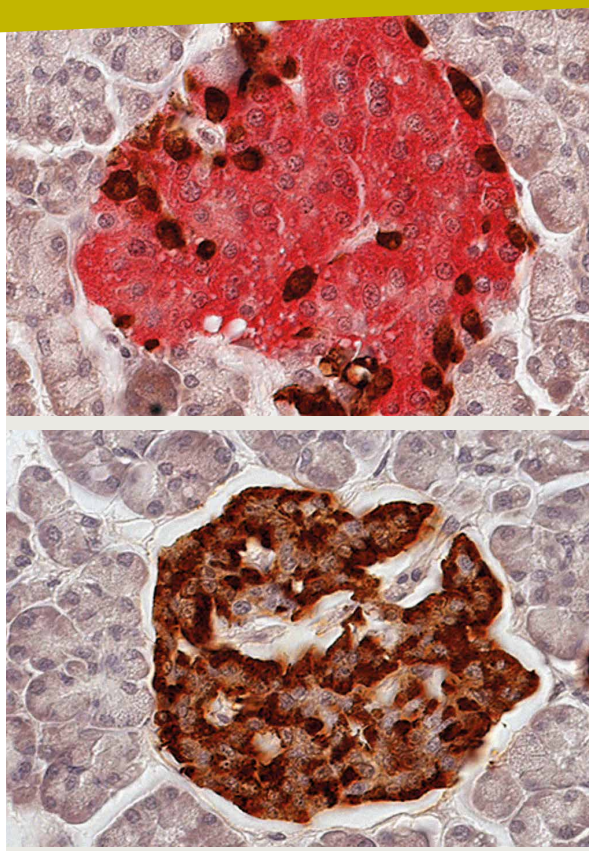
BetaGRAFT®: "Insulin on demand"

BETA-CELL is a privately owned bio-pharmaceutical company that develops novel cell therapies to treat the severe cases of diabetes. The company is a **spin-off of the Diabetes Research Center of the Vrije Universiteit Brussel (VUB-DRC). DRC is a leader in research on the biology of insulin-producing beta cells and its use as platform for developing novel methods for early diagnosis, prevention and treatment of diabetes.** DRC is an internationally recognized center of excellence in the field of diabetes with particular expertise in cell isolation and quality control, stem/precursor cell characterization and differentiation, preparation of standardized beta cell grafts and the organization and funding of multi-center clinical trials for diabetes patients. BETA-CELL's technology platform is based on prior, current and future work at the DRC. It has acquired proprietary technology for a first product line BetaPREP, and now combines this with BetaGRAFT® as its lead product. Recent developments have opened a second line, BetaSCREEN, in the field of drug screening and discovery using beta cells.

BETA-CELL is a partner of the Center for Beta Cell Therapy, an international consortium of research and clinical departments, reference centers and bioindustry, with coordination unit on the VUB-medical campus. This consortium undertakes a multidisciplinary program for the preservation and replacement of beta cells in type 1 diabetes patients. It designs strategies and develops methods, products and compounds that (1) help prevent the loss of insulin-producing cells at different phases of the disease process, (2) induce regeneration of beta cells in the pancreas and (3) produce therapeutic cell grafts at a large scale. Since its start in 2002, the Center receives international support from the Juvenile Diabetes Research Foundation (New York) and the European Union. As a biotechnology partner, BETA-CELL has privileged access to the new technologies and knowledge within this consortium, and to the implementation of its own products in the trials of the Center.

BETA-CELL

Spin-off
Vrije Universiteit Brussel



Pancreatic islet tissue in non-diabetic control (above) and in type 1 diabetic patient (below)

BETA-CELL's activities are part of a **joint effort with the DRC** towards the same objectives, **the company representing the biotech arm and DRC acting as research & development arm.** DRC has set up a clinically approved **BetaCellBank** for the standardized production of cell grafts from human donor organs; these are used in current treatment protocols since 1995. BETA-CELL rents laboratory and office space at the VUB-medical campus. This arrangement allows BETA-CELL to benefit from daily, direct access to state-of-the-art facilities and new developments at DRC, as well as to the BetaCellBank and its transplant trial team. This strategic alliance maximizes the efficiency of BETA-CELL's staff. The decision to continue BETA-CELL activities on the VUB-medical campus is important for further developments and compatible with the plan for a production and service facility at another site when higher production needs become necessary.

BETA-CELL uses these key assets **to initiate before the end of 2015 a clinical trial** with its BetaGRAFT product that is prepared from prenatal pig pancreases. **The clinical protocol will be based on observations that are currently collected by the DRC-team for transplants with encapsulated human beta cell grafts in type 1 diabetic patients.** The formulation of BetaGRAFT will meanwhile be further adjusted through studies in preclinical models. The beta cell transplant program coordinated by the DRC has been in operation since 1995 and is officially recognized by the Public Health Services in Belgium and by the Eurotransplant Foundation in Leiden. Novel clinical protocols are tested with the purpose of increasing efficacy and widening application. BETA-CELL will participate in a novel protocol which, when successful, will represent an important step towards the use of pig beta cells for the production of BetaGRAFT. The latter source is currently the only way for up-scaling the transplant activities to meet the clinical needs. BETA-CELL thus occupies a unique position in the development of beta cell grafts with wide applications, utilizing patented, validated and stringently tested products. Key features of the commercial BetaGRAFT are its ability to survive, function and grow in a selected micro-environment that includes a biocompatible barrier that protects the grafted cells from rejection and the host from possible side effects.

'Our porcine cell grafts are on their way to clinical trials in diabetes patients.'

Mike de Leeuw, CEO

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