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Companies To Watch: iTolerance

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Dedicated to curing diabetes and other conditions by inducing local immune tolerance in implantation

SNAPSHOT

iTolerance is in early development of a drug treatment that would eliminate the need for immunosuppression in implantation of islet cells to secrete insulin in patients with Type 1 diabetes. The treatment, coded iTOL- 100, suppresses activated T cells that would otherwise cause immune rejection of the transplanted cells. It does so by binding to the Fas receptor (FasR) on the activated T cells, causing them to die by apoptosis. iTolerance has completed mouse and non-human primate testing on the treatment with positive results. Other organ transplant programs, such as for the liver, are underway or under consideration.



Anthony Japour

WHAT'S AT STAKE

We started earlier this year taking closer looks at transplantation as a new therapeutic frontier and business space for biopharma. Now, following Jasper Therapeutics and Priothera, which had different approaches to transplanting blood stem cells, our eyes turn to a company plowing new ground in another area, Type 1 diabetes (T1D). That company is iTolerance, which has been at work for many years building the entire infrastructure needed to produce and test its treatment for T1D, a condition arising in the islets of Langerhans inside the pancreas, when the islet cells fail to produce insulin.

iTolerance arose out of patents and research work conducted by Dr. Andreas Garcia at Georgia Tech and Dr. Havalie Sherwan at the University of Louisville, both with grants from the Juvenile Diabetes Research Foundation (JDRF). With encouragement from JDRF, the two scientists joined forces to find a cure for T1D. After the successful primate tests, the company began to build operations in June 2021, when president and CEO Anthony Japour and chief scientist Camillo Ricordi joined. **“What attracted me first was the technology and the potential to translate it from the academic arena to a commercial product. That was exciting to me,”** Japour says. He also recognized a challenge: The FDA regulates donated islets as drugs, not as organs. “That has made it particularly difficult for this field to advance toward a product that could be reimbursed by insurance and patients could take.”

Japour is quick to add that the company also looks beyond the FDA: “We have a global regulatory strategy. We are not relying only on the FDA because we always have had a multipronged regulatory approach. We will definitely move forward in the U.S., but we are also looking at Canada and Europe and generally outside the U.S. to potentially accelerate clinical development.”

Japour agrees that bringing a biopharma solution into the transplantation space offers positive changes even as it presents challenges to the existing system. “Our approach combines two different disciplines — implantation and immune tolerance,” he says. “Our platform technology has the potential to harness the body’s own immune system to induce local immune tolerance, and that could really be a boon, not only for T1D but also for liver failure.” iTolerance is looking to apply its approach to other diseases, with several specific indications under consideration. “We’re starting with stem cells and allogeneic tissues where we can create a pocket of immune tolerance.”

iTolerance has come a long way toward establishing what would be a vast improvement in the transplantation space, but it also has a long way to go.

Vital Statistics

Employees: 3

Headquarters: Miami, FL

Finances:

\$17.1M Total Raised. Convertible Note.

Research partnerships:

LyGenesis: collaboration to evaluate combination of iTOL-201 and LyGenesis’ liver cell therapy (LYGLIV-100), for implantation and growth of ectopic livers without lifelong immunosuppression.

JDRF (Juvenile Diabetes Research Foundation): Industry Discovery and Development Partnership (IDDP)

Latest Updates

June 2022: iTolerance and LyGenesis joint research collaboration to regrow functioning, ectopic livers without immune suppression.

June 2022: iTolerance awarded IDDP with JDRF (up to \$850,000) for advanced preclinical development of iTOL-100 and iTOL-101 for Type 1 diabetes.

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