Stock|Interview.com

Feature

August 2006

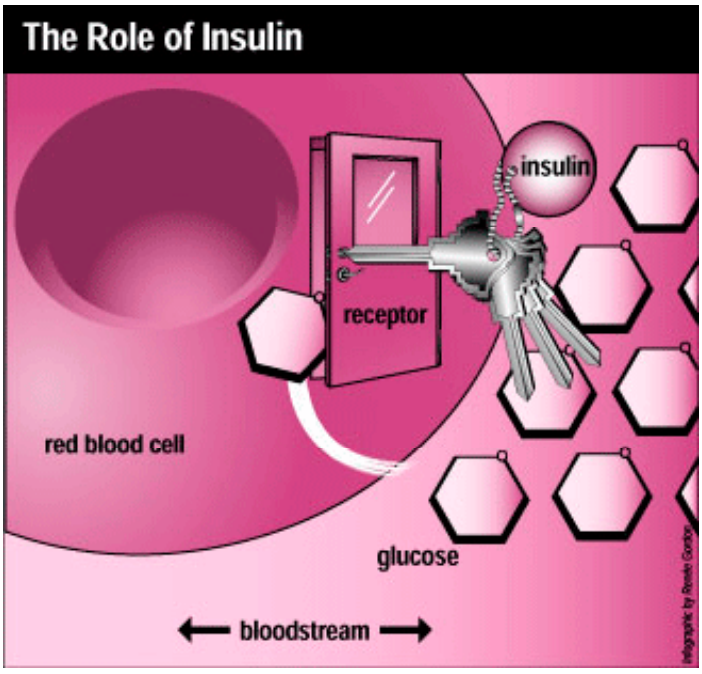
MASS MARKETING DIABETES REVERSAL

Novel Xenotransplants May Offer New Hope for Type 1 Diabetics

By James Finch

The problem has not been reversing diabetes. Since 1999, with the breakthrough 'Edmonton Protocol,' reversal of diabetes has been clinically proven to work. More than 80 percent of diabetics undergoing this transplant surgery were 'insulin free,' after three years. But, the hurdle which has eluded researchers thus far is the ability to provide broad commercial use of these transplant surgeries for the general population. New research may offer hope for a greater number of the 21 million diagnosed and potential diabetic sufferers.

Diabetes is the fifth leading cause of death in the United States. More than 200,000 die every year because of complications from diabetes. It is the leading cause of blindness and causes 40 percent of kidney failures. The small narrow organ behind your stomach, called the pancreas, breaks down nutrients by releasing enzymes into your small intestine. The pancreas releases insulin, which moves glucose into your cells to produce energy. In a Type 1 diabetic, the pancreas can no longer produce insulin, and the glucose stagnates in your bloodstream instead of being moved into your body cells to produce energy. About 10 percent of all diabetic cases, known as Type 1 diabetics, are at the highest risk for heart disease, strokes, limb amputations and other vascular disease-related complications. A Type 1 diabetic must inject insulin for his or her entire life.



The role insulin plays in bringing energy-producing glucose into the body's red blood cells. Courtesy of the U.S. Food and Drug Administration.

Before the Edmonton Protocol was developed at the University of Alberta, only eight percent of the 267 pancreatic islet cell transplant patients were able to remain free of insulin injections after a year. In Edmonton, Canadian surgeons developed a technique implanting healthy human islet cells into Type 1 diabetic patients who could then produce their own insulin. The ten-fold success rate increase became the industry standard for reversing diabetes, but there was a serious problem with this procedure. Transplantations were limited to high-risk Type 1 diabetics because of supply problems.

In this case, the broad divergence between the number of diabetics – about 80,000 per million, and the number of human donors – roughly 22 per million, made widespread commercialization of the Edmonton Protocol impossible. There simply aren't enough human donors available. Not by a long shot – at most, there may be less than 6,000 pancreatic donors compared to nearly 2 million Americans suffering from Type 1 diabetes. During a typical transplant, about one million islets would be required for a successful surgery in the average person. To obtain sufficient islets cells to perform this transplant procedure, at least two pancreatic organs are needed. Additional organs could be required to help the patient's insulin production reach the desired level.

University of Minnesota Reverses Diabetes in Monkeys

How are researchers remedying the supply shortage? Recent research demonstrates top scientists have turned to xenotransplantation to increase the number of islet cell donors. Another milestone took place at the University of Minnesota this past February when researchers at the Juvenile Diabetes Research Foundation islet transplant centers reversed diabetes in monkeys by transplanting islet cells from pigs. Researchers said pig organs are similar to those of humans. Pancreatic organs from pigs are more readily available to help save the life of a Type 1 diabetic. More than 60 million pigs were traded on the Chicago pork belly market last year, offering an abundance of pig islet cells for a much larger number of diabetic

transplant surgeries.

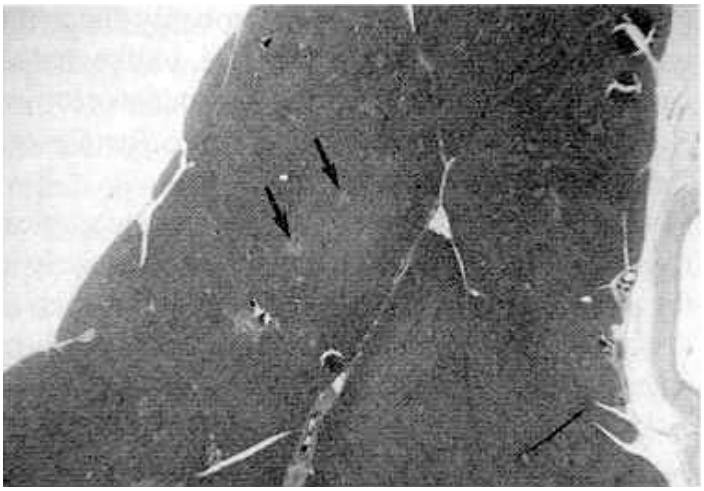
The novelty of the Minnesota research included a cocktail of immunosuppressive drugs which prevented the body's immune system from rejecting the cross-species transplant of the pig's islet cells. In the control group monkeys, which were not given immunosuppressive drugs, rejected the pig islets after a few days. While the drug mixture helped the lab monkeys survive much longer – a median of more than 140 days, the side effects of those drugs eventually caused their demise. Human subjects may demand a longer survival level after a transplant surgery.

We talked to Dr. David White, Novartis/Stiller Professor of Xenotransplantation at the University of Western Ontario, about the problem of organ rejection and the use of immunosuppressive drugs. "When it comes to animal-to human transplants, the amount of immunosuppressive drugs that you have to give to stop this rejection is dangerous to the patient," the renowned immunologist told us. "We've been looking for a way to transplant these islets without having to give these dangerous drugs." While at Cambridge University in the 1970s, Dr. White helped research and develop the immunosuppressive drug Cyclosporin A in conjunction with Professor Sir Roy Calne. The drug minimized the risk of organ rejection after transplantation, allowing new developments in transplantation procedures. Dr. White believes his current research may lead to a technique for performing the islet cell transplants without the use of immunosuppressive drugs.

Renowned Cambridge University researcher, Dr. David White, may be developing a new technique for broadly reversing diabetes in humans.

Research Innovation Could Lead to Widely Available Diabetes Reversal

This technique, which Dr. White believes may provide the final piece in the puzzle for insulin-dependent diabetics, is a refinement initially developed by Dr. Rafael Valdes, his former Cambridge University student. Valdes, who was featured in a five-part series on Canada's CTV TV in 2003, developed a subcutaneous tube for inserting Sertoli cells and islet cells into Type 1 diabetics. The Sertoli cells interfere with the immune system's rejection of the pig islet cells. Sertoli cells are found in the testicles and have, since 1939, been recognized as an 'immunologically privileged site.' In other words, surgeons can transplant into the testicles and not suffer organ rejection. By injecting Sertoli cells from pigs along with the pig islet cells, the body can accept the islet cells. The diabetic patient's



Histological view of a pig pancreas. Arrows point to the islets of Langerhans, which are used in Xenotransplants. Courtesy of the USDA.

rejuvenated pancreas can then produce insulin for his or her human body, successfully reversing the effects of Type 1 diabetes.

For the past six years, the Cambridge University surgeon has used this technique at his clinic in Mexico City, transplanting 24 human patients suffering from Type 1 diabetes. In more than half the cases, Valdes was able to reverse diabetes without the use of immunosuppression drugs. He continues to perform this procedure as authorized by the Mexican health authorities. The combination of Sertoli cells and islet cells from pigs are compatible with the human body's immune system, which eliminate the necessity of immunosuppression drugs to prevent the body's rejection of the transplanted cells.

"We're actually in the curious situation that we already have the clinical trials done, and now we're working on the pre-clinical studies," Dr. White told us. But this surgical procedure has not yet gotten FDA approval. "The critical issue is we're going to have to demonstrate reversal of diabetes in monkeys," White explained. "The question is how long the FDA will require us to reverse diabetes." FDA guidelines state 90 days, but Dr. White believes they may require between 6 months to a year of proven diabetic reversal on monkeys before the U.S. government agency will permit human clinical trials.

White presented a recent research breakthrough at the World Transplant Congress in Boston last month. "Along with everybody else, we had been using Sertoli cells taken from neonatal pigs," White told us. "We have discovered neonatal Sertoli cells are not nearly as effective as Sertoli cells taken from sexually mature adult pigs. We can demonstrate these are much better developed to fulfill their function of preventing rejection, and we have gotten good results with the adult Sertoli cells." He continues to use the islet cells from neonatal pigs in his innovative research, as did the University of Minnesota with their significant advance in reversing diabetics in monkeys.

While rodent trials are ongoing as a prelude to primate experiments, Dr. White has turned to the financial markets to complete his research and commercialize this treatment option for Type 1 diabetics. On May 25th, the Toronto Venture Exchange approved the Sernova Corp. [formerly Pheromone Sciences] (TSX: SVA) joint venture with Sertonex Inc. of London (Ontario) and Sertoli Tech-

nologies (Arizona) to develop a commercially viable treatment for Type 1 diabetes. Dr. White serves on the board of Pheromone, has been engaged as the principal researcher on this project and accepted the Chair of the company's scientific advisory board.

Since then, the company has begun adding scientific and business advisors to bring the project forward to commercialization. Formerly the Assistant Dean of Medicine at the University of Calgary, Dr. Norman Wong joined the Pheromone scientific advisory board in mid July to assist in product development of the diabetes treatment. Wong has published numerous articles on diabetic research and has researched the pathogenesis of diabetes mellitus. Two weeks later, Dr. Jannette Dufour joined the scientific board. She had previously worked at the University of Alberta's Clinical Islet Transplant Program (originators of the Edmonton Protocol for Type 1 diabetes). Dr. Dufour is presently also assistant professor at Texas Tech University.

It may be possible, after the company's commercialization process advances, that the much larger universe of Type 2 diabetics – especially those who are insulin-dependent – could benefit from this xenotransplantation technique. This number, in the United States alone, could exceed 12 million diabetics. According to the U.S. Center for Disease Control about 800,000 new cases of diabetes are diagnosed each year.

About $10 million dollars are spent on health care for diabetics every hour of the day. "We are looking at three to four million recipients initially with the number growing," said Dr. White of the xenotransplantation technique he is currently developing. As with many pioneering developments, further research, such as the work being conducted by Dr. White, builds upon the initial success of the Edmonton Protocol. In the near future, we may see a widely available treatment which can benefit a greater number of diabetics.

Websites and Trading Symbols of companies mentioned in this report:

Sernova Corp.	TSX: SVA	www.sernovacorp.com

Editor's Note:
Please visit StockInterview's disclaimer page http://www.stockinterview.com/disclaimer.html for full disclosure, forward looking statements, important links and cautions.