

Johnson & Johnson and Big Pharma Could Find a Diabetes "Cure" With PharmaCyte Biotech's Type 1 Diabetes Treatment

NEW YORK, NY -- (Marketwired) -- 02/08/16 -- Johnson & Johnson (J&J), like much of the biopharmaceutical industry worldwide, is aware of the desperate necessity for a Type 1 diabetes treatment. In fact, Diego Miralles, J&J's head of global innovation, said that his company's recent decision to partner with a privately held San Diego biotech was to "hedge our bets to make sure we would win in this space." Johnson & Johnson's deal with ViaCyte, Inc. is an effort to speed up the development of ViaCyte's stem cell treatment for Type 1 diabetes. Winning in the diabetes space, however, might mean that Johnson & Johnson or another larger company in the biopharmaceutical industry will need to take a long look at PharmaCyte Biotech (OTCQB: PMCB), a small Silver Spring, Maryland firm with its own Type 1 diabetes treatment.

After sitting in on PharmaCyte's second annual International Diabetes Consortium meeting in Vienna, Austria, it was clear that PharmaCyte has a treatment that many other companies, organizations and research institutes have yet to prove they're capable of producing. It is this treatment that Johnson & Johnson and other biopharmaceutical companies should be eyeing very closely. In order to pull off the feat of developing a successful treatment or "cure" for those who are insulin dependent, most researchers are looking for three key ingredients. And PharmaCyte has all three: (1) a cell line capable of producing insulin that can act as an "artificial pancreas," (2) an encapsulation technology that can house the cell line inside the body and keep it protected from the body's immune system, and finally (3) a team of experts in the diabetes arena that can bring the treatment to life.

PharmaCyte's treatment for type 1 diabetes and type 2 insulin-dependent diabetes is an encapsulated human cell line, called the Melligen cell line, which are liver cells that have been genetically modified to produce, store and release insulin in response to blood glucose levels in their surroundings. PharmaCyte will encapsulate the Melligen cells using its signature live-cell encapsulation technology, Cell-in-a-Box®.

Developing a successful diabetes treatment for Type 1 diabetics all starts with a cell line that is capable of producing insulin on demand. Unlike most who have turned to islet cells or stem cells, PharmaCyte has instead turned to Professor Ann Simpson, one of the 17 members on PharmaCyte's international diabetes consortium, and her colleagues at the University of Technology-Sydney in Australia. Professor Simpson and her team conducted numerous tests during the various stages of the development process and studies were carried out to show that Melligen cells secreted insulin in response to physiological concentrations of glucose (blood sugar). Furthermore, when Melligen cells were transplanted into diabetic mice whose immune systems were essentially not functioning, the blood

glucose levels of the mice became normal. This observation illustrates that Melligen cells can reverse the diabetic condition.

Their work was published in a major research article titled "Reversal of diabetes following transplantation of an insulin-secreting human liver cell line: Melligen cells" in the journal *Molecular Therapy - Methods & Clinical*

Development: <http://www.nature.com/articles/mtm201511>

The authors of the article note that, for the Melligen cells to be effective in treating Type 1 diabetes in humans where the insulin-producing beta cells of the pancreas have been destroyed, it will be necessary to protect these cells from rejection by the body's immune system after they have been introduced into the body. The article points out that one way to protect the Melligen cells would be to encapsulate the cells in protective "cocoons" prior to being placed into a diabetic patient. If this is done, the authors believe that encapsulated Melligen cells may offer a cure for Type 1 diabetes.

Enter step 2 of PharmaCyte Biotech's three-pronged approach, an encapsulation technology capable of protecting the genetically engineered live cells inside. The ability to encapsulate a cell line and keep it protected from immune system attack to treat diabetes has been called the "holy grail" of cell encapsulation. PharmaCyte's live-cell encapsulation technology, Cell-in-a-Box[®], appears to be the ideal encapsulation technology for this purpose. In fact, Melligen cells have already been successfully encapsulated using the Cell-in-a-Box[®] process, and the first preclinical studies have shown that Melligen cells are equally as safe inside the Cell-in-a-Box[®] capsules as the encapsulated cells that PharmaCyte will be using in its upcoming FDA human clinical trials in advanced pancreatic cancer.

So, with the Melligen cell line in place, and with Cell-in-a-Box[®] set to house the cell line to keep it protected, the final piece to developing a successful treatment for Type 1 diabetes is a team of experts who can put it all together, test it, modify the treatment where necessary, perfect the dosing in a number of animal models and get the treatment into clinical trials as quickly as possible.

PharmaCyte's CEO, Kenneth L. Waggoner, has assembled 17 experts in the field of diabetes from all over the globe. This group makes up PharmaCyte's International Diabetes Consortium. They have all come together to work toward one goal -- developing an "artificial pancreas" or a "cure" for insulin dependent diabetes. All of these experts are working at the same time in their specific area of expertise rather than waiting for each experiment to run its course before moving on to the next group of experts. It is this approach that should expedite PharmaCyte's path to human clinical trials. PharmaCyte's approach should provide answers more quickly for those larger biopharmaceuticals that expect to win the race to the first truly long-term successful type 1 diabetes treatment.

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Source: PharmaCyte Biotech, Inc.