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As Diabetes Becomes Global Epidemic, PharmaCyte Biotech's Insulin Producing Cells Receive 20 Years of Protection

NEW YORK, NY -- (Marketwired) -- 07/19/16 -- Worldwide the number of people living with diabetes has reached 422 million, and if the current trend continues, over 700 million people are expected to be living with diabetes by 2025. Diabetes has clearly become a healthcare crisis on a global scale, and PharmaCyte Biotech (OTCQB: PMCB) recently received some good news in the form of patent protection that will help the company do its part in bringing a treatment to tens of millions of these patients.

PharmaCyte recently learned from the U.S. Patent and Trademark Office (USTPO) that it now has 20 years of patent protection in the United States for the "Melligen" cells that are a part of the company's therapy for Type 1 and insulin-dependent Type 2 diabetes. The timing is perfect because the same research that laid out the dramatic rise in the numbers of people affected by diabetes, also found that the global cost of diabetes has ballooned to \$825-billion per year.

These staggering numbers come from the largest study ever done on diabetes levels across the globe. The study was published in the journal *The Lancet* and was led by scientists from Imperial College London, and involved Harvard T.H. Chan School of Public Health, the World Health Organization, and nearly 500 researchers across the globe, and it incorporated data from 4.4 million adults in most of the world's countries.

PharmaCyte's therapy for diabetes is made up of its signature live-cell encapsulation technology Cell-in-a-Box[®], which are pinhead-sized, porous capsules that are filled with insulin producing cells (Melligen cells). The capsules would protect the Melligen cells from destruction by the immune system and, in turn, would essentially create an "artificial pancreas" for type 1 diabetics and insulin-dependent type 2 diabetics that no longer produce their own insulin.

Prof. Ann. M Simpson and her colleagues at the University of Technology Sydney developed the Melligen cell line as an alternative to the transplantation of islets. According to Prof. Simpson and her team's research, which was published in the journal, *Molecular Therapy -- Methods & Clinical Development*, the cells are a human liver cell line that has been genetically engineered to reverse type 1 diabetes.
(<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 β cells of the pancreas have been destroyed, it will be necessary to protect those 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.

It was PharmaCyte's Cell-in-a-Box[®] that got the attention of Prof. Simpson and her colleagues as the ideal encapsulation technology. In a 6-month study, pancreatic islet cells from pigs were encapsulated using the Cell-in-a-Box[®] capsules. Those capsules containing the islet cells were then implanted into live, diabetic rats. Within only a few days, the blood-sugar levels of the diabetic rats became normal and stayed at normal levels for the entire study.

When the capsules were removed from the rats at the end of the study, the islet cells inside the capsules were still alive and functioning. Pigs were chosen as the source for the pancreatic islet cells because biologically they are the closest to humans. Because islet cells from pigs ("foreign" donors) could be implanted in rats without the cells being rejected, this proves the islet cells inside PharmaCyte's Cell-in-a-Box[®] capsules were protected from attack by the rats' immune systems.

So now that the Melligen cells have received the patent protection necessary in both the United States and Europe, the marriage between the Cell-in-a-Box[®] capsules and the Melligen cells is in the hands of PharmaCyte's International Diabetes Consortium, which consists of world-renowned physicians and scientists from a number of countries around the world, all of whom share the same goal of developing a treatment for insulin-dependent diabetes.

Watch PharmaCyte's video on the development of its diabetes treatment at:
www.PharmaCyte.com/diabetes.

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