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PharmaCyte Biotech to Change Future of Treating Diseases with Validation of Encapsulation Technology in Pancreatic Cancer Trial

NEW YORK, NY, Oct. 28, 2019 (GLOBE NEWSWIRE) -- PharmaCyte Biotech (OTCQB: PMCB) has a technology that could very well change the way a host of hard-to-treat diseases are treated for the foreseeable future. The company is closer than ever to its upcoming Phase 2b clinical trial in locally advanced, inoperable pancreatic cancer (LAPC) that could give patients a new lease on life by shrinking their tumors enough so that the tumors can be removed surgically. It is an outcome that would not go unnoticed.

Clinical trials are essential for the development of new treatments, and PharmaCyte will enter this upcoming trial with two essential goals in mind—the future of its pancreatic cancer treatment and the future of its technology. First, successfully shrinking tumors would address a real unmet medical need for a group of patients that no longer realizes any benefit from either of the two first-line therapies. Second, and of equal importance for the small California-based biotech, will be to utilize the company's first-ever clinical trial to validate or prove that its signature live-cell encapsulation technology, Cell-in-a-Box®, is both effective and safe to use in humans.

When asked about the importance of validating its technology in a clinical trial setting in relation to the company's future, PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said, "PharmaCyte is on the precipice of completely changing the paradigm for how diseases are treated in the future. New cell lines are constantly being developed to treat a variety of diseases, particularly genetically engineered cells lines. With the validation of our technology, Cell-in-a-Box® knows no bounds in helping these cell lines succeed in treating a disease in the way the cell line was designed to treat it."

During PharmaCyte's clinical trial, it will introduce its Cell-in-a-Box® technology to a public that is mostly unfamiliar with it and how it works. Cell-in-a-Box® refers to a porous microcapsule that acts as a "protective cocoon" for the more than 20,000 genetically modified live cells inside. If this cellular therapy proves it can shrink tumors in a large group of patients during an FDA trial, while at the same time proving that the technology can remain where it's placed inside the body and the cells inside the capsules can remain viable, it would certainly be welcomed news that would reverberate throughout the pancreatic cancer community—and likely well beyond that.

Commenting on PharmaCyte's clinical trial, renowned oncologist and clinician Dr. Manuel Hidalgo, who will be the Principal Investigator for the trial, said, "The primary goal of the study is to determine the efficacy of this approach, compared to a standard of care treatment, in controlling LAPC. If this endpoint is met, the technology will be validated as a

therapeutic option in patients with LAPC."

Dr. Hidalgo also knows the significance of shrinking tumors in patients with LAPC and stated, "Patients who undergo a successful operation may be indeed cured of the disease. So, if this strategy is able to increase the number of patients that can undergo surgery to remove their previously inoperable tumors, that could be a very important finding."

Prof. Walter H. Gunzburg, the co-founder and Chief Technical Officer of Austrianova, said of targeted cellular therapies and specifically Cell-in-a-Box®, which Austrianova helped to develop, "This is the future of medicine, this is the new generation of how we're going to be able to treat diseases—not only cancer but a whole plethora of other diseases. We're going to be able to take cells; we're going to program them to do what we want, and we're going to put them back into patients' bodies and they're going to react to signals in the patient to produce medicines in the right way. So, what PharmaCyte is doing and what we're doing with PharmaCyte is we're actually taking the first few bold steps for the new medicines for the next generation."

Validating the Cell-in-a-Box® technology in an FDA clinical trial will confirm that PharmaCyte has a role in shaping the future of treating diseases using cellular therapies. As monumental as it would be for PharmaCyte to shrink what were once considered inoperable tumors to the point that they are now made operable, validation of the technology is equally as monumental for patients worldwide who suffer from other hard-to-treat diseases and who could now find hope in Cell-in-a-Box® to specifically treat some of those diseases.

PharmaCyte's Chief Operating Officer, Dr. Gerald W. Crabtree, commenting on the upcoming clinical trial said, "Validating the technology simply means that we may have open to us a way to treat diseases for which any type of human cell can be employed—for example, stem cells. All that is needed is that the cells be pure and free from adventitious agents, so validating our technology would mean they can be derived from another human and/or genetically modified."

When Dr. Crabtree offers stem cells as an example, obviously a treatment for Type1 and insulin-dependent Type 2 diabetes has to be one of the hard-to-treat diseases at the forefront of his thinking. After all, an encapsulation technology that can live inside the body —staying exactly where that technology is implanted and acting as a protective home for the insulin-producing cells inside without any threat from the body's immune response (eliminating the need for harmful immunosuppressive drugs), all while delivering insulin to diabetic patients—is considered the "Holy Grail" for a diabetes treatment, a disease that represents the largest healthcare crisis in the world.

Dr. Crabtree added, "The clinical trial in LAPC, if successful, will prove that the Cell-in-a-Box® capsules with genetically altered human cells inside them are safe to use in other human beings. This safety aspect is very important to the FDA and this is why we have made it one of two primary objectives in our clinical trial protocol. A successful trial should also put to rest any doubts about whether the capsules can protect the cells inside from the body's immune system attack for a reasonable amount of time."

Dr.'s Crabtree and Hidalgo agree that the treatment of numerous different cancers could very well be the future for both PharmaCyte and Cell-in-a-Box® once the technology is

validated. Dr. Crabtree points to the results of a published Phase 1/2 study using the Cell-in-a-Box® technology in dogs that developed spontaneous mammary tumors as evidence that certain types of breast cancer where there are discrete tumor nodules could be a target for the technology.

Dr. Hidalgo expanded the list of possibilities saying, “As this technology is extremely versatile in the sense that different cell types with different genetic manipulations can be used, the range of cancer types that can be treated is vast. It is envisioned that this clinical trial will open the opportunity to explore the same technology in other hard-to-treat cancers like liver, cholangiocarcinoma, head and neck cancer, brain tumors and others. Furthermore, the range of cells that can be encapsulated in Cell-in-a-Box® as well as the genetic modifications that can be made to these cells is just huge.”

And the list doesn’t stop there. In addition to potential treatments for a number of cancers and for diabetes using different types of cells, the list of treatments grows exponentially when we discuss stem cells. In addition to encapsulating stem cells to treat diabetes, the encapsulation of stem cells can also be used to regenerate and repair diseased or damaged tissues in patients. These stem cell therapies are available for people with spinal cord injuries, Parkinson’s disease, Alzheimer’s disease, heart disease, strokes, burns and even cancer.

Researchers continue to develop new ways in which stem cells can be conducive to better regenerative medicine approaches, to be eventually applied in transplants. Again, protecting stem cells using PharmaCyte’s technology would solve the long-standing concern over safety and efficacy of stem cell therapy to treat diseases and conditions of organs and tissues in patients.

Today’s healthcare market offers few effective ways to treat the root causes of many diseases or conditions. In many cases, typical treatments can only manage a patients’ symptoms with medications or devices, providing only temporary symptomatic relief.

PharmaCyte’s CEO believes that validating Cell-in-a-Box® will open many doors to the future of cellular therapies for his company. “What PharmaCyte is involved with can lead to a game-changing approach to treating numerous degenerative diseases. By encapsulating certain types of stem cells and protecting them, the body is given a chance to heal itself. This type of therapy is the future of medicine—medicine that offers the realistic promise of repairing damaged tissue and reversing the effects of many degenerative conditions, offering solutions for people with diseases that today are beyond repair.”

It's clear that cellular therapies could offer PharmaCyte a real opportunity to: (i) expand its own pipeline; (ii) partner with other biotechnology and pharmaceutical companies on the development of cellular treatments; and/or (iii) entertain suitors for specific indications, who have an eye on developing their own treatment(s)—all contingent upon Cell-in-a-Box® performing as well as it has in the past and validating itself once and for all on the world’s biggest stage, an FDA clinical trial.

To learn more about PharmaCyte’s pancreatic cancer treatment and how it works inside the body to treat locally advanced inoperable pancreatic cancer, watch the company’s documentary video complete with medical animations at:

https://www.PharmaCyte.com/Cancer

About PharmaCyte Biotech

PharmaCyte Biotech, Inc. is a biotechnology company developing cellular therapies for cancer and diabetes based upon a proprietary cellulose-based live-cell encapsulation technology known as "Cell-in-a-Box®." This technology will be used as a platform upon which therapies for several types of cancer and diabetes are being developed.

PharmaCyte's therapy for cancer involves encapsulating genetically engineered human cells that convert an inactive chemotherapy drug into its active or "cancer-killing" form. For pancreatic cancer, these encapsulated cells are implanted in the blood supply to the patient's tumor as close as possible to the site of the tumor. Once implanted, a chemotherapy drug that is normally activated in the liver (ifosfamide) is given intravenously at one-third the normal dose. The ifosfamide is carried by the circulatory system to where the encapsulated cells have been implanted. When the ifosfamide flows through pores in the capsules, the live cells inside act as a "bio-artificial liver" and activate the chemotherapy drug at the site of the cancer. This "targeted chemotherapy" has proven effective and safe to use in past clinical trials and results in little to no treatment related side effects.

PharmaCyte's therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes involves encapsulating a human cell line that has been genetically engineered to produce and release insulin in response to the levels of blood sugar in the human body. PharmaCyte is developing the use of genetically modified liver cells and stem cells, as well beta islet cells, to treat diabetes. The encapsulation will be done using the Cell-in-a-Box® technology. Once the encapsulated cells are implanted in a diabetic patient, they will function as a "bio-artificial pancreas" for purposes of insulin production.

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