September 22, 2015

PharmaCyte Biotech Discusses Pancreatic Cancer Treatment for Upcoming Phase 2b Human Clinical Trial

SILVER SPRING, Md., Sept. 22, 2015 (GLOBE NEWSWIRE) -- PharmaCyte Biotech, Inc. (OTCQB:PMCB), a clinical stage biotechnology company focused on developing targeted treatments for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, released today the first in a series of articles that will serve to educate the public on its technology and how it is used in the treatment of advanced pancreatic cancer. These articles will be written by doctors, scientists and oncologists who are associated with PharmaCyte Biotech's upcoming Phase 2b clinical trial. This first educational piece is authored by PharmaCyte Biotech's Chief Operating Officer, Dr. Gerald W. Crabtree, with the goal of explaining PharmaCyte Biotech's treatment.

What is Cell-in-a-Box®?

With so many telephone calls, emails and articles describing our technology and our treatment for pancreatic cancer incorrectly, as PharmaCyte Biotech's Chief Operating Officer and resident scientist, I felt it was imperative to help our shareholders and the public understand what our technology is and how it works before we head into our clinical trial in humans. First, our signature live-cell encapsulation technology, Cell-in-a-Box®, does not encapsulate and deliver drugs to treat pancreatic cancer.

Cell-in-a-Box® is the name given to a technology by which genetically modified living human cells are encapsulated in tiny capsules or "protective cocoons." The outer shell or the capsule is made mainly of cotton, or more specifically of cellulose. The capsules are not designed to, and cannot be used to, enclose small molecules such as drugs.

The capsules have a diameter of the size of the head of a pin. The outer shell of each capsule has tiny openings in it. These openings are large enough to let nutrients enter into the capsule and feed the live cells inside, and are large enough to allow waste products and beneficial products produced by the cells to leave the capsule. But these openings are too small to let the cells inside the capsule leave. The cells inside the capsules thrive as they consume nutrients, oxygen and other molecules delivered by the blood supply. Most importantly, the openings in the outer shell of the capsules are too small to let a patient's immune system cells into the capsules. If this were not the case, the cells of the body's immune system would get inside and rapidly destroy the cells inside.

What Types of Cells are Encapsulated for the Treatment of Pancreatic Cancer?

The cells that are encapsulated to treat pancreatic cancer are human cells that have been genetically modified to produce an enzyme that causes a biochemical reaction to take place. In humans, this is part of an enzyme system known as the cytochrome P450 system.

The cytochrome P450 system in humans causes a biochemical reaction to take place in the liver. Once an inactive chemotherapy drug comes in contact with the liver through the blood circulatory system, an inactive chemotherapy drug is converted from its inactive form to its active or “cancer-killing” form.

What Drug is used with the Encapsulated Cellsto Treat Pancreatic Cancer?

PharmaCyte Biotech uses ifosfamide to kill cancer cells in a patient with advanced pancreatic cancer. Ifosfamide is a prodrug – meaning it needs to be activated before it is able to kill cancer cells. The activation of ifosfamide into its “cancer-killing form” is normally done by the cytochrome P450 enzyme system in the liver. That is not the case with PharmaCyte Biotech’s treatment for pancreatic cancer. As explained below, the activation takes place before ifosfamide reaches the liver and right at the source of the cancer.

What is PharmaCyte Biotech’s Pancreatic Cancer Treatment and How Does it Work?

PharmaCyte Biotech’s pancreatic cancer treatment consists of implanting encapsulated genetically modified live cells as close to the tumor as possible and then giving a patient ifosfamide so that the conversion of the ifosfamide takes place as close to the tumor as possible. Each capsule contains approximately 10,000 genetically modified cells, which efficiently convert ifosfamide into its cancer-killing form. Ifosfamide is given to a patient at one-third the normal dose after the encapsulated cells have been implanted. This conversion enables the highest concentration of ifosfamide to be converted at or near the tumor - rather than where it is normally converted – in the liver.

The first step in the treatment is to implant 300 of the capsules as close to the tumor as possible. This is done by threading a catheter up through an artery in the leg leading to the pancreas. This process is done by a special type of radiologist known as an interventional radiologist. When the catheter is in place, the capsules are injected through the catheter and placed at or near the tumor in the pancreas. It is then that low-doses of ifosfamide are given to a patient intravenously. The ifosfamide is carried by the circulatory system to where the encapsulated cells have been implanted. When the ifosfamide comes into contact with the encapsulated live cells, the cells activate the ifosfamide to its cancer killing form. This activation takes place at the source of the cancer, delivering the highest concentration of ifosfamide to attack the cancer cells. This activation occurs before the ifosfamide has even reached the liver. Because ifosfamide is given at one-third the normal dose, there are no side effects from PharmaCyte Biotech’s treatment.

Is PharmaCyte’s Pancreatic Cancer Treatment Effective?

In a previous clinical trial in elderly, very sick patients with advanced, inoperable pancreatic cancer, PharmaCyte Biotech’s treatment proved to be both effective and safe. When the data from the trial were compared with historical data for the drug gemcitabine, the only drug approved at the time to treat pancreatic cancer, the encapsulated genetically modified live cells plus low-dose ifosfamide combination treatment was superior in anticancer effect to gemcitabine in terms of median survival time of the patients and in terms of the percentage of one-year survivors. Furthermore, no treatment-related side effects were reported with this treatment compared to significant treatment-related side effects with the gemcitabine therapy.

What is the Next Step for PharmaCyte Biotech?

PharmaCyte Biotech is preparing to conduct a Phase 2b clinical trial where the Cell-in-a-Box® plus low-dose ifosfamide combination will be given to patients with locally advanced pancreatic cancer. If successful, the Cell-in-a-Box® plus low-dose ifosfamide treatment may become an effective option for patients with advanced pancreatic cancer – one of the world's deadliest forms of cancer – that we believe will fulfill a longstanding unmet medical need. More will be explained about this when we disclose the design of the trial.

About PharmaCyte Biotech

PharmaCyte Biotech is a clinical stage biotechnology company focused on developing and preparing to commercialize treatments for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®" This unique and patented technology will be used as a platform upon which treatments for several types of cancer, including advanced pancreatic cancer and its symptoms, and diabetes are being developed.

PharmaCyte Biotech's treatment for cancer involves encapsulating genetically modified live cells capable of converting an inactive chemotherapy drug (ifosfamide) into its active or "cancer-killing" form. Ifosfamide is normally activated in the liver. These encapsulated live cells are placed as close to a cancerous tumor as possible. Ifosfamide is then given intravenously at one-third the normal dose. It is carried by the circulatory system to where the encapsulated cells have been placed. When the ifosfamide comes in contact with the encapsulated live cells, activation of the drug takes place before it gets to the liver at or near the tumor without any side effects from the chemotherapy. This "targeted chemotherapy" has proven remarkably effective and safe to use in past clinical trials.

In addition to developing a novel treatment for cancer, PharmaCyte Biotech is developing a treatment for Type 1 diabetes and Type 2 insulin-dependent diabetes. PharmaCyte Biotech plans to encapsulate a human cell line which has been genetically engineered to produce, store and secrete insulin at levels in proportion to the levels of blood sugar in the human body. The encapsulation will be done using the Cell-in-a-Box® technology.

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This press release may contain forward-looking statements regarding PharmaCyte Biotech and its future events and results that involve inherent risks and uncertainties. The words "anticipate," "believe," "estimate," "expect," "intend," "plan" and similar expressions, as they relate to PharmaCyte Biotech or its management, are intended to identify forward-looking statements. Important factors, many of which are beyond the control of PharmaCyte Biotech, could cause actual results to differ materially from those set forth in the forward-looking statements. They include PharmaCyte's ability to continue as a going concern, delays or unsuccessful results in preclinical and clinical trials, flaws or defects regarding its product candidates, changes in relevant legislation or regulatory requirements, uncertainty of protection of PharmaCyte Biotech's intellectual property and PharmaCyte Biotech's continued ability to raise capital. PharmaCyte Biotech does not assume any obligation to update any of these forward-looking statements.

More information about PharmaCyte Biotech can be found atwww.PharmaCyte.com. It can also be obtained by contacting Investor Relations.

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