

PharmaCyte Biotech Clinical Trial Designed to Expand Standard of Care Therapy for Pancreatic Cancer

SILVER SPRING, Md., Oct. 21, 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[®], announced today the new trial design for its upcoming clinical trial in patients with advanced pancreatic cancer using PharmaCyte's treatment (Cell-in-a-Box[®] + low-dose ifosfamide chemotherapy).

The overall goal of the trial is to determine whether PharmaCyte's pancreatic cancer treatment can satisfy a critical unmet medical need by acting as a consolidation therapy for patients who no longer respond to the combination of nab-paclitaxel (Abraxane[®]) + gemcitabine – currently the “gold standard” for the treatment of pancreatic cancer. Treatments for this group of patients are only marginally effective. The trial will compare the effectiveness of PharmaCyte's pancreatic cancer treatment “head-to-head” using several criteria with one of the commonly used treatments for these patients - the combination of the cancer drug capecitabine (Xeloda[®]) + x-radiation. Capecitabine, which can be given orally, is a “prodrug” form of the widely used chemotherapeutic agent 5-fluorouracil (5-FU) that is given intravenously.

The trial will be conducted in the United States, with study sites in Europe and Australia. Eligible patients will be randomly placed into two groups. The patients in Group 1 will receive PharmaCyte's pancreatic cancer treatment. The patients in Group 2 will receive treatment with the combination of capecitabine + x-radiation. Two of the most important factors in the trial design are: (i) the eligibility criteria for accepting patients into the trial; and (ii) the factors to be considered to determine whether PharmaCyte's treatment has been successful in achieving its goals (endpoints).

- a. Eligibility Criteria: The patients accepted into the trial must have pancreatic cancer that is inoperable, but that has not yet spread from the pancreas where it first started to another place in the body (metastatic cancer). These patients must also have tumors that no longer respond to the combination chemotherapy treatment of Abraxane[®] + gemcitabine and that have been on the treatment for a period of between four and six months.
- b. Endpoints of the Trial: The primary endpoints will be: (i) progression-free survival; and (ii) the side effects from the treatment that occur in the patients. Progression-free survival (PFS) is the time that elapses from the first day of treatment until the disease gets worse. PFS will be determined at 6 and 12 months. The occurrence of any side effects will be monitored throughout the trial.

The trial design also includes several secondary endpoints. Among the most important are: (i) the onset of pain and the patient's need for pain medications; (ii) whether the inoperable tumors become operable as a result of the treatment; (iii) the change in tumor size; and (iv) the patient's overall quality of life during the treatment.

The design of the trial was a collaborative effort between PharmaCyte, Translational Drug Development (TD2), America's premier Contract Research Organization (CRO) specializing in oncology, world renowned oncologists Dr. Mathias Löhr of the famed Karolinska Institute in Stockholm and the Chairman of PharmaCyte's Scientific Advisory Board, and Dr. Manuel Hidalgo, Director of Clinical Research at the Spanish National Cancer Research Center and a member of PharmaCyte's Scientific Advisory Board.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said of the newly designed trial, "The design of our upcoming clinical trial was truly a collaborative effort among world renowned experts in oncology and science. In the trial design, personnel at TD2, Dr. Löhr, Dr. Hidalgo and Dr. Korn at Imaging Endpoints have shown why they have been on the forefront of developing new oncology drugs for advanced pancreatic cancer in innovative ways that can best treat patients with this dreadful disease. By working together as a team, they have accelerated the timeline for getting our pancreatic cancer treatment into the marketplace and have addressed a critical unmet medical need. We could not be more pleased with the trial new design."

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 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. These encapsulated live cells are placed as close to a cancerous tumor as possible. Once implanted in a patient, ifosfamide is then given intravenously at one-third the normal dose. The ifosfamide is carried by the circulatory system to where the encapsulated cells have been placed. When ifosfamide, which is normally activated in the liver, comes in contact with the encapsulated live cells, activation of the drug takes place at the source of the cancer 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 that 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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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 at www.PharmaCyte.com. It can also be obtained by contacting Investor Relations.

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