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PharmaCyte Executives Meet With Translational Drug Development to Advance Pancreatic Cancer Clinical Trial

SILVER SPRING, Md., Jan. 25, 2016 (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 that its Chief Executive Officer, Kenneth L. Waggoner, and its Chief Operating Officer, Dr. Gerald W. Crabtree, recently met with principals of Translational Drug Development (TD2) at TD2's facilities in Scottsdale, Arizona. The meeting was held to discuss a number of aspects related to PharmaCyte's upcoming clinical trial in pancreatic cancer and the structure of the Investigational New Drug Application (IND) that must be submitted to the FDA and found acceptable before the clinical trial can begin. PharmaCyte has contracted with TD2 to be the lead Contract Research Organization (CRO) to prepare for and conduct PharmaCyte's clinical trial in pancreatic cancer.

In its clinical trial, PharmaCyte's pancreatic cancer treatment (microcapsules containing live cells that convert the cancer prodrug ifosfamide into its cancer-killing form together with low doses of ifosfamide) will be compared with the combination of the cancer drug capecitabine plus radiation therapy. The clinical trial will be an open-label, "two-armed," randomized multi-site trial.

The morning session addressed how the clinical trial will be structured and conducted. It was determined that there will be several cancer centers in the United States, with a number of study sites in Europe and possibly Australia. Discussions also dealt with suggested changes related to the number of patients in each arm of the trial, inclusion/exclusion criteria for patients that will be enrolled in the trial and possible sites at which the trial will be conducted.

The afternoon session focused on the IND and the timeline for filing it with the FDA. The afternoon session also included discussions related to the content and preparation of the Chemistry, Manufacturing and Controls (CMC) section of the IND. The CMC section is a pivotal part of the IND and will be a major focus of the FDA when it examines PharmaCyte's IND submission. TD2 and Chamow & Associates (Chamow) will both prepare the CMC section of the application. Chamow has already performed an inspection and audit of Austrianova's live-cell encapsulation facility in Bangkok, Thailand. That is the facility where the genetically modified live cells will be encapsulated using the Cell-in-a-Box[®] technology that are part of PharmaCyte's pancreatic cancer treatment.

In commenting on the sessions at TD2, Waggoner stated, "These face-to-face meetings with TD2's clinical trial team were extremely important and exceedingly helpful to PharmaCyte in finalizing the design of the clinical trial. We believe they will prove to be invaluable as we move forward with the preparations for our upcoming clinical trial in pancreatic cancer. The interactions that we had with the team at TD2 in this one day alone reinforce our belief that,

in TD2, we have the finest CRO available in which to put our trust that PharmaCyte's clinical trial will be prepared and conducted as well as it could be."

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's treatment for cancer involves encapsulating genetically modified live cells that convert 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 is developing a treatment for Type 1 diabetes and Type 2 insulin-dependent diabetes. PharmaCyte plans to encapsulate a human cell line that has been genetically engineered to produce, store and release insulin in response to the levels of blood sugar in the human body. The encapsulation will be done using the Cell-in-a-Box[®] technology.

Safe Harbor

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 or its management, are intended to identify forward-looking statements. Important factors, many of which are beyond the control of PharmaCyte, 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's intellectual property and PharmaCyte's continued ability to raise capital. PharmaCyte does not assume any obligation to update any of these forward-looking statements.

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

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