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# PharmaCyte Biotech Designs Clinical Trial to Meet Critical Unmet Medical Need

## Trial to Include Pancreatic Cancer Pain Study

SILVER SPRING, Md., Oct. 14, 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<sup>®</sup>, announced today that its upcoming clinical trial will determine whether its pancreatic cancer treatment (Cell-in-a-Box<sup>®</sup> capsules + low-doses of ifosfamide) can satisfy a critical unmet medical need for patients with pancreatic cancer when the “gold standard” treatment is no longer effective at treating the disease. Currently there is no adequate alternative treatment available.

Translational Drug Development (TD2), along with Dr. Matthias Löhr of the famed Karolinska Institute in Stockholm, Sweden, and the Chairman of PharmaCyte Biotech’s Scientific Advisory Board, and Dr. Manuel Hidalgo, the Director of Clinical Research at the Spanish National Cancer Research Center and a member of PharmaCyte’s Scientific Advisory Board, provided invaluable information and guidance to PharmaCyte in the design of its clinical trial in advanced pancreatic cancer. The trial is designed to provide an effective treatment for the large percentage of patients who no longer respond to the “gold standard” for the treatment of advanced pancreatic cancer. There are few options for further treatment available to them, and these are only marginally effective. PharmaCyte’s team believes that it is here that PharmaCyte’s pancreatic cancer treatment could play an important role in what has been termed a “consolidation therapy” in the further treatment of these patients.

As previously explained by Dr. Löhr in his recent article on the unmet medical need being targeted by PharmaCyte, chemotherapy may be able to prevent relapse in patients whose pancreatic cancer tumors have been removed surgically, but this situation occurs in only 20% of all patients at best. The large remaining group of patients whose tumors are inoperable normally receive treatment designed to prolong survival. Recent progress in the chemotherapy of pancreatic cancer has resulted in survival rates of between 10 and 11 months through the use of either the combination of gemcitabine and nab-paclitaxel (Abraxane<sup>®</sup>), the “gold standard” for the treatment of pancreatic cancer, or a harsh combination of conventional cancer chemotherapy drugs known as FOLFIRINOX that not all patients can tolerate.

However, for patients whose tumors neither progress nor show signs of tumor reduction, there is no effective treatment alternative. PharmaCyte’s treatment of pancreatic cancer may fill this critical unmet medical need for these patients. This need and opportunity caused PharmaCyte to completely redesign its clinical trial.

In addition to examining the antitumor effectiveness of PharmaCyte’s pancreatic cancer treatment, the effect of the treatment on the development and progression of the pain

associated with pancreatic cancer will also be measured in the clinical trial. Because this “pain” aspect will be studied, it will no longer be necessary to conduct a separate “pain” clinical trial as originally planned. The pain associated with pancreatic cancer is both unbearable and untreatable in about 25% of patients with the disease.

PharmaCyte Biotech’s Chief Executive Officer, Kenneth L. Waggoner, commented, “We are extremely grateful to TD2, Dr. Löhr and Dr. Hidalgo for their insight and guidance in designing our clinical trial. We believe that their identification of the opportunity for our pancreatic cancer treatment to satisfy a critical unmet medical need will give our pancreatic cancer treatment the greatest opportunity for success. The inclusion of the previously planned separate pain trial in the upcoming trial will also eliminate the need for a costly and time-consuming separate trial to study this aspect of our pancreatic cancer treatment. Over the next week or so, we will be laying out our new trial design and the other changes related to the upcoming clinical 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 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 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.

### **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 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](http://www.PharmaCyte.com). It can also be obtained by contacting Investor Relations.

Investor Relations:  
PharmaCyte Biotech, Inc.  
Investor Relations Department  
Telephone: 917.595.2856  
Email: [Info@PharmaCyte.com](mailto:Info@PharmaCyte.com)



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