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PharmaCyte Biotech End of Year Shareholder Update on Pancreatic Cancer and Diabetes Programs

SILVER SPRING, Md., Dec. 30, 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 a shareholder update on PharmaCyte's pancreatic cancer and diabetes programs.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, highlighted the following developments since the Company's last shareholder update:

- PharmaCyte announced a complete redesign of its clinical trial in advanced pancreatic cancer. After consulting with world-renowned experts in the field of pancreatic cancer; including, Dr. Mathias Löhr, Dr. Manuel Hidalgo, and experts at Translational Drug Development (TD2), PharmaCyte's Phase 2b clinical trial was completely redesigned in an attempt to satisfy a critical unmet medical need that exists for patients with inoperable, but not metastatic, pancreatic cancer whose tumors no longer respond after 4 to 6 months of treatment with the current "gold standard" for the disease, the combination of Abraxane[®] plus gemcitabine. In most cases, therapy consisting of another chemotherapy agent plus radiation is given to such patients. However, the beneficial effects of these treatments are marginal at best.
- The clinical trial will now be conducted in the United States by TD2 with study sites in both Europe and Australia.
- Eligible patients will be randomly placed into two groups. Group 1 will receive PharmaCyte's pancreatic cancer treatment of Cell-in-a-Box[®] plus low doses of ifosfamide. Group 2 will receive treatment with the combination of capecitabine + radiation.
- The primary endpoints for the trial will be: (i) progression-free survival (PSF); and (ii) the side effects that occur in the patients. PSF is the time that elapses from the first day of treatment until the disease gets worse. The trial design also includes several secondary endpoints; the most important of which 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 patients' overall quality of life during the treatment.
- PharmaCyte will now include in this trial the evaluation of its pancreatic cancer treatment on the treatment of pain, a severe consequence of pancreatic cancer. A

separate clinical trial on pancreatic cancer pain is no longer necessary.

- Regarding PharmaCyte's work on ascites fluid production and accumulation, a series of additional preclinical studies has been initiated and are being continued by TD2. The initial studies using an ovarian tumor model in mice indicated that PharmaCyte's pancreatic cancer treatment might have value in treating the malignant ascites fluid condition. These preclinical studies are now being continued with other abdominal tumor models, beginning with colon cancer, in an effort to better define the conditions under which PharmaCyte's pancreatic cancer treatment can modulate the production or accumulation of malignant ascites fluid.
- In late 2015, PharmaCyte obtained the Orphan Drug designation (ODD) for its pancreatic cancer treatment from the European Medicines Agency (EMA). With this designation, PharmaCyte now has ODD in Europe and the United States, which was obtained in late 2014 when the FDA granted the ODD to PharmaCyte. Obtaining the ODD allows for 10 years of marketing exclusivity in the European Union and 7 years of marketing exclusivity in the United States upon approval by the EMA and the FDA of PharmaCyte's pancreatic cancer treatment.
- PharmaCyte appointed Dr. Manuel Hidalgo as a member of its Scientific Advisory Board and as a consultant. For several years, Dr. Hidalgo worked closely with pancreatic cancer expert Dr. Daniel D. Von Hoff, Chief Development Officer of TD2. Recently, Dr. Hidalgo was appointed Head of Hematology and Oncology at the Beth Israel Deaconess Hospital in Boston, an institution that is affiliated with the renowned Dana-Farber Cancer Institute in Boston.
- PharmaCyte contracted with Imaging Endpoints, one of America's leading Contract Research Organizations for radiologic imaging, to perform the radiologic imaging that will be the cornerstone of many of the measurements conducted during the pancreatic cancer clinical trial.
- Prior to the initiation of a clinical trial, an Investigational New Drug Application (IND) must be filed and reviewed by the FDA. A major part of the IND is a section termed "Chemistry, Manufacturing and Controls" or "CMC." Within the CMC section, a pivotal portion describes the characteristics of the drug or treatment production facility and supplies supporting documentation to ensure that the facility meets cGMP standards. PharmaCyte retained CMC experts Chamow and Associates (Chamow) to assist in evaluating the facility in Bangkok, Thailand, that will produce and supply the Cell-in-a-Box[®] technology for PharmaCyte's clinical trial, and in preparing the relevant portions of the CMC section of the IND for submission to the FDA and other regulatory agencies. PharmaCyte and TD2 are awaiting receipt of Chamow's audit report to finalize the timeline for commencement of the clinical trial.
- In November 2015, the second annual meeting of the international Diabetes Consortium was held in Vienna, Austria. Members of the Consortium presented results of studies done to date and finalized research plans for future studies. A video that discusses PharmaCyte's diabetes program was filmed at the meeting and can be viewed at www.PharmaCyte.com/diabetes.

- A guest at the meeting of the Diabetes Consortium was Prof. Dr. Hans-Peter Hammes, one of Europe's leading authorities on diabetes and its complications. Dr. Hammes currently serves as Section Head of Endocrinology at the 5th Medical Department, University Medical Center Mannheim at the University of Heidelberg in Germany. Dr. Hammes received the prestigious Camillo Golgi Prize awarded at the 2015 meeting of the European Association for the Study of Diabetes. After attending the Diabetes Consortium meeting and becoming acquainted with the Consortium members, Dr. Hammes agreed to join PharmaCyte's Scientific Advisory Board and become a member of the Consortium. Dr. Hammes also agreed to serve as a consultant to PharmaCyte.

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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