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PharmaCyte Biotech Announces Pre-IND Meeting Date with FDA

LAGUNA HILLS, Calif., Jan. 04, 2017 (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®, today announced that it will be meeting with the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (FDA) on Tuesday, January 17, 2017. The meeting is to discuss numerous aspects of PharmaCyte's planned clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, commenting on the meeting said, "We are pleased that PharmaCyte will be starting out the New Year with a meeting with CBER. PharmaCyte has submitted a list of important questions to the FDA that will be essential to the design of our trial and how it is to be conducted. The questions also touch on the need for any additional information to be developed or submitted to the FDA before PharmaCyte files its Investigational New Drug application (IND). We are looking forward to CBER's responses so that we can continue with our product development of an effective and safe therapy for LAPC."

PharmaCyte recently submitted questions to the FDA as part of its pre-IND submission package. With answers to these questions and any additional information provided by CBER during the January 17 meeting, PharmaCyte will address any open issues or requests of CBER before preparing its IND. Once the IND is submitted and found to be acceptable to the FDA, PharmaCyte can proceed with its planned clinical trial in LAPC and enroll patients at the selected trial sites throughout the U.S.

PharmaCyte's clinical trial in patients with LAPC is designed to meet a clear unmet medical need for those whose cancer no longer responds after 4-6 months of treatment with the combination of Abraxane® plus gemcitabine. The trial will be open-label and multi-site in nature - with sites in the U.S. and Europe. Patients with LAPC will be randomized equally into two groups. One group will receive gemcitabine chemotherapy alone, and the other group will receive PharmaCyte's pancreatic cancer therapy (encapsulated genetically modified live human cells that can activate the cancer prodrug ifosfamide plus low doses of ifosfamide to eliminate side effects from the chemotherapy). In addition to comparing the anticancer activity and safety of the two therapies, a major aspect of the trial will be to determine if, and how well, PharmaCyte's therapy can shrink inoperable tumors so that they become operable.

About PharmaCyte Biotech

PharmaCyte Biotech a clinical stage biotechnology company developing therapies for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." This technology will be used as a platform upon which therapies

for several types of cancer and diabetes are being developed. PharmaCyte's therapy for cancer involves encapsulating genetically engineered human cells that convert an inactive chemotherapy drug into its active or "cancer-killing" form. These encapsulated cells are implanted as close to the patient's cancerous tumor as possible. Once implanted, a chemotherapy drug that is normally activated in the liver (ifosfamide) is given intravenously at one-third the normal dose. The ifosfamide is carried by the circulatory system to where the encapsulated cells have been implanted. When the ifosfamide comes in contact with the encapsulated cells they act as an artificial liver and activate the chemotherapy drug at the source of the cancer. This "targeted chemotherapy" has proven effective and safe to use in past clinical trials and results in no side effects.

In addition to developing a novel therapy for cancer, PharmaCyte is developing a treatment for Type 1 diabetes and insulin-dependent Type 2 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. Once the encapsulated cells are implanted in a diabetic patient they will function as a "bio-artificial pancreas" for purposes of insulin production.

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

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