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# PharmaCyte Biotech Submits Pre-IND Meeting Package to FDA

LAGUNA HILLS, Calif., Dec. 15, 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 it has submitted its pre-Investigational New Drug (pre-IND) meeting package to the U.S. Food and Drug Administration (FDA) for PharmaCyte's therapy in inoperable locally advanced pancreatic cancer (LAPC). PharmaCyte's pre-IND submission follows its recent announcement that the FDA has granted PharmaCyte a pre-IND meeting for its pancreatic cancer therapy.

The package provides the FDA with a full history of PharmaCyte's therapy, including information on the previous preclinical studies and the clinical trials that were performed using the Cell-in-a-Box® live-cell encapsulation technology combined with low doses of the chemotherapy drug ifosfamide. That combination makes up PharmaCyte's pancreatic cancer therapy. The package also provides detailed information on the manufacturing process used to produce the Cell-in-a-Box® capsules and a synopsis of the structure of the clinical trial that PharmaCyte plans to conduct in the U.S. and Europe in patients with inoperable LAPC.

The FDA's response to the pre-IND submission will be provided after the pre-IND meeting. The regulatory agency's response will serve as a roadmap in guiding PharmaCyte as it prepares the full IND application that must be deemed acceptable to the FDA before the clinical trial can begin.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, commented, "The submission of the pre-IND package is yet another major step that PharmaCyte has completed in its efforts to develop its pancreatic cancer therapy. We are looking forward to the pre-IND meeting and the FDA's guidance as we prepare for our clinical trial in patients with inoperable LAPC where there is an unmet medical need we plan to address."

**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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