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PharmaCyte Biotech Requests Pre-IND Meeting with FDA for its Pancreatic Cancer Clinical Trial

LAGUNA HILLS, Calif., Nov. 01, 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®, today announced that it has submitted a request for a pre-IND meeting with the U. S. Food and Drug Administration (FDA) for its planned clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

PharmaCyte has submitted questions to the FDA as part of a pre-IND meeting request where aspects of the content of the Investigational New Drug (IND) application itself (CMC section, clinical trial description, etc.) will be discussed. After the FDA has responded to the questions and issued comments, PharmaCyte must address them to the FDA's satisfaction. A review of PharmaCyte's responses by the FDA will then take place at the formal pre-IND meeting where final agreement between PharmaCyte and the FDA on all aspects discussed will be reached. With this information, the IND will be submitted by PharmaCyte and reviewed by the FDA. Once the IND is found to be acceptable to the FDA, patients can be enrolled in PharmaCyte's clinical trial.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said of the meeting request, "We are pleased that PharmaCyte has taken the first step towards regulatory approval in the United States of its therapy for LAPC. When I started to lead this company in January 2014, my first goal was to surround our technology with the best of the best in the biotech sector. I believe we have more than accomplished this goal as we have compiled an internationally renowned team that will lead PharmaCyte into what we expect to be a pivotal human clinical trial. My second goal was to get our therapy to the FDA, and with this pre-IND meeting request, we have accomplished this goal as well. My ultimate goal, of course, was and is to get our pancreatic cancer therapy into clinical trials and approved by the FDA. I feel we are well on our way to accomplishing this goal."

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 the prodrug 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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