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PharmaCyte Biotech Discusses Major Milestones Ahead of Phase 2b Clinical Trial in Pancreatic Cancer

SILVER SPRING, Md., Sept. 15, 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®, discussed today some of the major "milestone" tasks that must be completed to begin its Phase 2b clinical trial in pancreatic cancer. The trial will test the effectiveness and safety of PharmaCyte Biotech's pancreatic cancer treatment. This treatment consists of the combination of microcapsules with genetically modified live cells in combination with low doses of the chemotherapy drug ifosfamide. These encapsulated live cells are placed as close to a cancerous tumor as possible to enable the delivery of the highest levels of the cancer-killing drug at the source of the patient's cancer.

In the coming weeks and months, a number of major "milestone" tasks will take place that will enable PharmaCyte Biotech's first clinical trial to commence. Many of these must be completed before a formal Investigational New Drug application ("IND") is filed with the drug regulatory authorities.

- Finalization of Trial Design: With pivotal input from PharmaCyte Biotech's renowned team of oncologists, the design of its clinical trial will be finalized with the goal of creating the highest probability of developing positive data during the trial that could lead to marketing approval of its treatment for pancreatic cancer.

- IND Team: An IND Team will be established to prepare the IND and review it before being formally submitted to the regulatory authorities. PharmaCyte Biotech's IND Team, many of whom have already been retained, will include: (i) a Project Manager; (ii) a Medical Officer; (iii) a Statistician; (iv) a Chemistry, Manufacturing and Controls Expert; (v) a Pharmacologist; (vi) a Pharmakineticist; (vii) a Toxicologist; (viii) an Interventional Radiologist; (ix) a Radiologist; and (x) a Regulatory Affairs person.

- Chemistry, Manufacturing and Controls Information: The manufacturing of investigational biological products are subject to stringent regulatory considerations. PharmaCyte Biotech will be working with Austrianova – the manufacturer of the encapsulated live cells used in PharmaCyte Biotech's treatment for pancreatic cancer – to develop this information.

- Clinical Protocol: A "protocol" will be prepared with by its Contract Research Organization with the invaluable assistance of PharmaCyte Biotech's team of oncologists. The clinical protocol can be viewed as a "recipe" on how the clinical trial will be conducted. The protocol will include such things as: (i) the qualifications needed for particular patients to be included in the trial; (ii) how PharmaCyte Biotech's

treatment and the treatment used in the “comparator” arm of the study will be administered and the schedule and duration of these treatments; (iii) the specific “endpoints” for the trial and the types of data that will be collected to determine these endpoints; and (iv) the types of data analysis that will be employed in reaching conclusions about the overall success of the trial.

- Pre-IND Meeting: This meeting will be requested by PharmaCyte Biotech and initiates communication with the drug regulatory authorities that will be responsible for approving its product to market. This communication is particularly important for a company like PharmaCyte biotech that is developing a new product or technology. The purpose of a pre-IND meeting is to discuss the information that will be used to prepare the IND, such as product characterization, final and in-process testing of the product, previous animal test data, prior clinical trial data and the proposed clinical protocol. Input from the regulatory authorities given during the pre-IND meeting will lead to “fine-tuning” the clinical trial protocol and will identify any additional items that may need to be included in the IND.

- Clinical Trial Study Sites: Clinical study sites will be evaluated and enrolled to participate in the clinical trial. Each site will need to be multidisciplinary in nature, where medical oncologists, interventional radiologists, radiologists and other cancer specialists work together to offer multidisciplinary cancer treatments and who will work in concert in conducting their part of the clinical trial.

- IND: An Investigational New Drug application will be submitted to the drug regulatory authorities before PharmaCyte Biotech can begin the clinical trial. The IND will include animal study data, toxicity (side effects that cause great harm) data, manufacturing information, the clinical protocol for the trial, data from any prior human clinical trials and information about the Principal Investigator who will oversee all aspects of the trial.

PharmaCyte Biotech’s Chief Executive Officer, Kenneth L. Waggoner, commented on the process underway at the company, “A well thought out clinical trial design and program is critical for the long-term effectiveness of efforts to bring our treatment for pancreatic cancer through the regulatory approval process. Bringing a new cancer therapy through the approval process requires an in depth understanding of the complex drug development process and the integral role that each member of our team plays in that process. Proper planning and addressing the critical steps in the development of that process are essential. Because of our outstanding team of oncologists and our other team members, we believe that we are taking measures to avoid unnecessary expenses and barriers in navigating our treatment to a successful conclusion.”

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, including advanced pancreatic cancer and its symptoms, and diabetes are being developed.

PharmaCyte Biotech's treatment for cancer involves encapsulating genetically modified live cells capable of converting the prodrug ifosfamide into its active or "cancer-killing" form. These encapsulated live cells are placed as close to a cancerous tumor as possible to enable the delivery of the highest levels of the cancer-killing drug at the source of the cancer. Ifosfamide is then given intravenously at one third the normal dose. When the ifosfamide comes in contact with the encapsulated live cells through the circulatory system, the activation of the drug takes place at or near the tumor without any side effects. This "targeted chemotherapy" has proven remarkably effective and safe to use in past clinical trials.

In addition to developing treatments for cancers, 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 on demand 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. It can also be obtained by contacting Investor Relations.

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