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PharmaCyte Biotech Strengthens Protection of Cancer Therapy with Patent Filing

LAGUNA HILLS, Calif., March 22, 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 has filed a provisional patent application with the United States Patent and Trademark Office (USPTO) to protect its therapy to treat cancerous tumors, including the therapy that will be used in its upcoming clinical trial in locally advanced pancreas cancer (LAPC).

The patent application specifically includes methods of treating all cancerous tumors, such as pancreas, liver, breast and colon, using the live-cell encapsulation of genetically modified human cells that overexpress a form of the Cytochrome P450 enzyme system normally found in the liver. These cells are encapsulated using the Cell-in-a-Box® technology. Together with low doses of ifosfamide, the encapsulated cells comprise PharmaCyte's therapy for cancerous tumors. The patent application also includes using PharmaCyte's platform technology with cyclophosphamide, another chemotherapy drug that must be activated by the Cytochrome P450 enzyme system.

"By filing for a new patent, we have begun taking steps to obtain patent protection for 20 years to protect our therapy for all forms of malignant tumors. This is particularly important to the company as we are taking steps to embark upon a clinical trial in pancreas cancer," said PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner. "We will be filing for new patent protection in all of the countries in which PharmaCyte currently has patent protection for pancreas cancer."

Provisional patent applications are a way to establish and protect a "date of invention" or "priority filing date" for one year. The provisional patent application was created to provide inventors with a way to begin protecting their inventions. A provisional patent application provides PharmaCyte 12 months to prepare a full patent application during which it can label its inventions as "patent pending." It also enables PharmaCyte to establish an early effective filing date for a patent.

The family of patents that deal with the subject matter of the new patent application are set to expire on March 27, 2017. The new patent application is designed to continue patent protection of PharmaCyte's therapy for cancerous tumors. It is not an extension of the existing patents. A new patent for PharmaCyte's cancer therapy, if granted by the USPTO, will provide another 20 years of patent protection from the date of the filing of this Provisional Patent Application - March 21, 2017.

PharmaCyte therapy for pancreas cancer is already protected. PharmaCyte's pancreas

cancer therapy was designated an orphan drug and listed in the official registry of medicinal products for rare diseases by the U.S. Food and Drug Administration (FDA) on December 17, 2014. This orphan drug status assures marketing exclusivity for PharmaCyte's pancreas cancer therapy in the U.S. for 7 years after market approval by the FDA. Similarly, PharmaCyte has orphan drug status in the European Union (EU) for its pancreas cancer therapy. This designation provides 10 years of marketing exclusivity in all countries in the EU following approval by the European Medicines Agency (EMA).

In addition, the Biologics Price Competition and Innovation Act (BPCIA), which was enacted as part of the Affordable Care Act in 2010, establishes a period of 12 years of "data exclusivity" for reference products to preserve incentives for future innovation. Under this framework, data exclusivity protects the data in the innovator's regulatory application by prohibiting others, for a period of 12 years, from gaining FDA approval based in part on reliance on or reference to the innovator's data in a biosimilar application. PharmaCyte's 12-year exclusivity will begin as soon as the FDA approves the company's pancreas cancer therapy.

Mr. Waggoner concluded by stating, "While this patent application should make our investors feel assured about the protection of our pancreas cancer therapy, they should understand that if our pancreas cancer therapy receives FDA approval, the orphan drug designation in the U.S. and the EU, together with the BPCIA data exclusivity, will give us substantial marketing exclusivity for our pancreas cancer therapy. This new patent application, while it does include our pancreas cancer therapy, should really be viewed as an opportunity to dramatically broaden PharmaCyte's ability to protect our therapy for all malignant tumors for the next 20 years."

About PharmaCyte Biotech

PharmaCyte Biotech is 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 contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of risk factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

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

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