February 4, 2020

PHARMACYTE BIOTECH

PharmaCyte Biotech Will Have All the Protection It Needs for Pancreatic Cancer Treatment Upon Marketing Approval

NEW YORK, NY, Feb. 04, 2020 (GLOBE NEWSWIRE) -- PharmaCyte Biotech (OTCQB: PMCB) is about to embark upon a planned U.S. FDA Phase 2b clinical trial to treat locally advanced, inoperable pancreatic cancer (LAPC) at trial sites all over the United States, and with that journey comes the need to keep its signature technology, Cell-in-a-Box®, protected should it one day receive marketing approval from drug regulatory agencies in the U.S. and Europe. PharmaCyte's Cell-in-a-Box® technology for the treatment of pancreatic cancer is certainly protected well into the future if/when it does receive the coveted marketing approval it's striving for upon the completion of clinical trials.

Currently, PharmaCyte is revamping its provisional patent application and its strategy related to full patent protection. The idea is to present the United States Patent and Trademark Office (USPTO) with an acceptable provisional patent application that protects its therapy to treat cancerous tumors, including the therapy that will be used in its upcoming clinical trial in LAPC.

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, and an approved provisional patent application will provide PharmaCyte 12 months to prepare a full patent application. This approach will offer the company an opportunity to establish an early effective filing date for a patent.

A provisional patent—and eventually a full patent—would give PharmaCyte a fresh 20 years of patent protection; however, even without it, PharmaCyte has protections in place to protect its technology that are in line with any biotechnology/pharmaceutical company developing treatments after many years. In most cases, the 20-year patent protection that biotechnology/pharmaceutical companies have in place while developing drugs/treatments, have their 20-year time frame cut in half to 10 years by the time the drug hits the marketplace.

Patents are typically awarded within a few years after the patent application submission, but a common misconception is that the patent begins only after the drug hits the market, so with this in mind, PharmaCyte will actually have longer protections in place than most biotechnology/pharmaceutical companies have upon marketing approval after years of development.

How is this possible? Well, actually PharmaCyte has two protections in place that will keep its technology protected—and unlike 20-year patent protection where the clock is ticking throughout development, these protections don't begin until the therapy is approved. First,

PharmaCyte is developing a “biologic” therapy, which offers protections under the Affordable Care Act, and second, PharmaCyte’s therapy for pancreatic cancer was granted Orphan Drug Designation from both the U.S. FDA and in the European Union by the European Medicines Agency (EMA).

PharmaCyte’s pancreatic cancer therapy was designated an orphan drug and listed in the official registry of medicinal products for rare diseases by the U.S. FDA on December 17, 2014. This orphan drug status assures marketing exclusivity for PharmaCyte’s pancreatic cancer therapy in the U.S. for 7 years after market approval by the FDA. Also, PharmaCyte has orphan drug status in the European Union (EU) for its pancreatic 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 doesn’t begin until the FDA approves the company’s pancreatic cancer therapy.

PharmaCyte’s Chief Executive Officer, Kenneth L. Waggoner, said of the protections for the company’s pancreatic cancer therapy, “If our pancreatic 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 pancreatic cancer therapy. Any new patent application, while it does include our pancreatic 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.”

To learn more about PharmaCyte’s pancreatic cancer treatment and how it works inside the body to treat locally advanced inoperable pancreatic cancer, watch the company’s documentary video complete with medical animations at:
https://www.PharmaCyte.com/Cancer

About PharmaCyte Biotech

PharmaCyte Biotech, Inc. is a biotechnology company developing cellular 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. For pancreatic cancer, these encapsulated cells are implanted in the blood supply to the patient’s tumor as close as possible to the site of the tumor. 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 flows through pores in the capsules, the live cells inside act as a “bio-artificial liver” and activate the chemotherapy drug

at the site of the cancer. This “targeted chemotherapy” has proven effective and safe to use in past clinical trials and results in little to no treatment related side effects.

PharmaCyte’s therapy for Type 1 diabetes and insulin-dependent Type 2 diabetes involves encapsulating a human cell line that has been genetically engineered to produce and release insulin in response to the levels of blood sugar in the human body. PharmaCyte is developing the use of genetically modified liver cells and stem cells, as well beta islet cells, to treat diabetes. 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.

About Stock Market Media Group

Stock Market Media Group is a Content Development IR firm offering a platform for corporate stories to unfold in the media with press releases, research reports, corporate videos, radio-style CEO interviews and feature news articles.

This article was written based upon publicly available information. Stock Market Media Group may, from time to time, include our own opinions about the companies, their business, markets and opportunities in our articles. Any opinions we may offer about any of the companies we write about are solely our own and are made in reliance upon our rights under the First Amendment to the U.S. Constitution, and are provided solely for the general opinionated discussion of our readers. Our opinions should not be considered to be complete, precise, accurate, or current investment advice, or construed or interpreted as research. Any investment decisions you may make concerning any of the securities we write about are solely your responsibility based on your own due diligence. Our publications are provided only as an informational aid, and as a starting point for doing additional independent research. We encourage you to invest carefully and read the investor information available at the web site of the U.S. Securities and Exchange Commission at: www.sec.gov, where you can also find all of PMCB’s filings and disclosures. We also recommend, as a general rule, that before investing in any securities, you consult with a professional financial planner or advisor, and you should conduct a complete and independent investigation before investing in any security after prudent consideration of all pertinent risks. We are not a registered broker, dealer, analyst, or advisor. We hold no investment licenses and may not sell, offer to sell or offer to buy any security. Our publications about PMCB are not a recommendation to buy or sell a security.

Stock Market Media Group and its management may benefit from any increase in the share price of the profiled companies and hold the right to sell the shares bought at any given time including shortly after the release of the company’s profile. Section 17(b) of the 1933 Securities and Exchange Act requires publishers who distribute information about publicly traded securities for compensation, to disclose who paid them, the amount, and the type of payment. Under the Securities Act of 1933, Section 17(b), Stock Market Media Group discloses that it expects to be remunerated fifteen thousand dollars monthly from September 2019 to September 2020, paid for by a third party via bank wire, to produce content related to PharmaCyte. This article is the opinion of Stock Market Media Group and was written based upon publicly available information and interviews conducted by SMMG.

Stock Market Media Group does not own any shares in PharmaCyte and never accepts compensation in free-trading shares for its marketing services of the company being profiled,

however third parties that might have compensated Stock Market Media Group may hold free-trading shares of the company being profiled and could very well be selling, holding or buying shares of the company's stock at the same time the content is being disseminated to potential investors; this should be viewed as a definite conflict of interest and as such, the reader should take this into consideration.

If Stock Market Media Group ever accepts compensation in the form of free trading shares of the company being profiled and decides to sell these shares into the public market at any time before, during, or after the release of the company's profile, our disclaimer will be updated accordingly reflecting the current position of those free trading shares received as compensation for our services.

For more information: www.stockmarketmediagroup.com

Contact:

Stock Market Media Group

info@stockmarketmediagroup.com

Source: PharmaCyte Biotech