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PharmaCyte Biotech Discusses Protection Strategy for Cancer and Diabetes Therapies

SILVER SPRING, Md., March 15, 2016 (GLOBE NEWSWIRE) -- PharmaCyte Biotech, Inc. (OTCQB:PMCB), a clinical stage biotechnology company focused on developing targeted therapies for cancer and diabetes using its live-cell encapsulation technology, Cell-in-a-Box®, presents today another in a series of articles that will serve to educate the public on its live-cell encapsulation technology and its use in developing treatments for pancreatic cancer and diabetes. This educational piece addresses PharmaCyte's intellectual property (IP) and the strategy that PharmaCyte will employ to protect that property.

PharmaCyte's IP consists of exclusive license agreements that PharmaCyte has with other parties and IP that PharmaCyte intends to create during the clinical development of its product candidates. In the questions and answers below, PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, discusses PharmaCyte's IP protection strategy, which consists of patents, patent term extensions, regulatory data exclusivity, market exclusivity for orphan drugs, know-how/trade secrets and trademarks.

PharmaCyte's Intellectual Property Protection Strategy

Which family of patents protects PharmaCyte's pancreatic cancer therapy and what is your plan to extend those patents?

"Before I answer that question, let me say that our pancreatic cancer therapy has two iron-clad protections that will far surpass any protection that our patents could ever bring if we can obtain FDA approval. I will discuss this a little later in this piece, but keep in mind while reading these responses that our pancreatic cancer therapy is going to remain protected long after the patents expire.

"Everyone interested in PharmaCyte's pancreatic cancer therapy should be focused on the family of patents that deal with the live-cell encapsulation of genetically altered human cells that overexpress a form of the Cytochrome p450 enzyme system (normally found in the liver), and specifically on only 2 patents in that family. Those patents are set to expire in the United States a little over a year from now on March 27, 2017. These are the only patents that pertain to PharmaCyte's pancreatic cancer therapy. Now, while these patents are set to expire next year, we certainly aren't sitting idly by and allowing that to happen.

"We do have a protection strategy in place, which includes filing an application with the U.S. Patent and Trademark Office for interim extensions extending the life of those patents 1 year at a time for up to 5 years, which we believe will be long enough to get us through clinical trials and the regulatory approval process. The earliest the application can be filed is 6 months before the expiration of the patents, and the application can be filed up to 15 days

before the expiration date. PharmaCyte can and plans to file its patent extension application between September 27, 2016, and March 12, 2017."

Can PharmaCyte apply for follow-on patents? If so, can you explain what these patents are?

"Yes. New patentable inventions related to a pharmaceutical product, also called 'follow-on patents,' generally encompass improvements to, or new uses for, the pharmaceutical not disclosed or suggested in the original patent. PharmaCyte anticipates extending its patent protection for its product candidates through improvements to its core technology, including:

1. New Formulations: New formulations of a known drug compound that are clinically superior to the previous drug formulation may be patentable. Developing new formulations that promote a patient's successful therapy through such things as reduced dosing or ease of use, or that exhibit improved therapeutic outcomes or more favorable side-effect profiles, are patentable. Examples include sustained-release formulations, extended-release formulations and dosing regimens.

2. New Routes of Administration: Additional patent protection may be obtained for new formulations that permit new routes of administration.

3. New Uses: Patents directed to new uses and treatments may be obtained.

4. Combinations: Combining two or more drugs into one treatment also may be patentable.

New discoveries that may be eligible for patent protection as follow-on patents cannot be predicted at the current time; however, PharmaCyte anticipates improvements to its technology and product candidates to be generated as these product candidates move through clinical testing."

Being that PharmaCyte's cancer product candidates are biologics, does PharmaCyte qualify for regulatory data protection and the 12 years of data exclusivity that comes with it as outlined by the Biologics Price Competition and Innovation Act (BPCIA), which was enacted as part of the Affordable Care Act in 2010?

"Yes. This is one of the two iron-clad protections that I was speaking of earlier in this article. We will be seeking this protection and the 12 years of data exclusivity it provides. 'Reference product exclusivity' or 'regulatory data protection' is an IP right available for a limited duration, which protects an innovator's proprietary safety and efficacy data for its innovative product. This protection prevents any other party, during an exclusivity term of 12 years, from relying on the innovator's proprietary data in order to obtain marketing approval or authorizations for a follow-on 'biosimilar' or generic drug product. A biosimilar product is a follow-on version of an innovator's biological product.

"PharmaCyte's cancer product candidates are considered biological products because the capsules that are part of those products contain living, albeit genetically altered, human cells. Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapies, tissues and recombinant

therapeutic proteins. The BPCIA created an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product.

“The BPCIA establishes a period of 12 years of data exclusivity for reference products in order 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 their biosimilar application. PharmaCyte anticipates its 12-year exclusivity will begin as soon as the FDA approves its pancreatic cancer product candidate.

“Countries in the European Union (EU) also provide for such data protection. Further, in October 2015 it was agreed as part of the Trans-Pacific Partnership trade deal between the United States, Australia, Brunei, Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam that biologic drugs will be given a minimum of 5 years data exclusivity.”

Can you explain how the Orphan Drug designation that PharmaCyte has received in both the United States and in the European Union is a major source of protection for PharmaCyte’s pancreatic cancer therapy?

“This is the second of the two protections I spoke of earlier. PharmaCyte’s pancreatic cancer product candidate was designated an orphan drug and listed in the official registry of medicinal products for rare diseases by the FDA on December 17, 2014. This orphan drug status assures market exclusivity for PharmaCyte in the United States for 7 years after market approval. Similarly, PharmaCyte has orphan drug status in the EU for its pancreatic cancer product candidate. This designation provides 10 years of market exclusivity in all of the countries in the EU and assistance from the EMA in the product development.

“So it should be understood that once we gain market approval, our pancreatic cancer therapy will have exclusive protections with both the regulatory data protection and the orphan drug designations. In addition, there are a number of know-how/trade secrets and trademark protections built in that we believe will make it exceedingly difficult for any company or entity to ever duplicate our pancreatic cancer therapy and complete clinical trials before we reach market approval. Conservative estimates have indicated that, given the complex nature of the trade secrets/know-how associated with our IP portfolio, we may be able to extend the protection of our IP portfolio by at least several years on this basis alone.”

In addition to PharmaCyte’s pancreatic cancer therapy, PharmaCyte also has a diabetes therapy that it is developing that will need protecting. Can you discuss how you’ll protect the therapy that consists of Cell-in-a-Box® and Melligen cells?

“PharmaCyte has a License Agreement with the University of Technology Sydney (UTS) in Australia that provides PharmaCyte with an exclusive worldwide right to use genetically modified human liver cells called ‘Melligen cells.’ Those cells have been modified to contain pancreatic islet cell glucokinase for use in developing a treatment for Type 1 diabetes and insulin-dependent Type 2 diabetes. The Melligen cells are protected by a patent issued in the EU that is in the process of being validated in each of the major countries. In addition, there is a patent pending in the United States. The License Agreement also provides PharmaCyte with the non-exclusive worldwide rights to ‘know-how’ associated with the

Melligen cells.

“PharmaCyte also licensed from Austrianova the exclusive, worldwide rights to use the Cell-in-a-Box® cellulose-based live-cell encapsulation technology for the development of a treatment for diabetes and the use of Austrianova’s Cell-in-a-Box® trademark for this technology. The diabetes Licensing Agreement grants PharmaCyte exclusive worldwide rights to use the Cell-in-a-Box® technology with genetically modified or non-modified non-stem cell lines, designed to produce insulin and/or other critical components for the treatment of diabetes.”

In simple terms, how would you summarize PharmaCyte’s strategy for protecting its IP portfolio?

“PharmaCyte has several diverse avenues available to it for protecting its IP portfolio. We plan to pursue all of these in order to extend our IP portfolio to the greatest extent possible.”

About PharmaCyte Biotech
PharmaCyte Biotech is a clinical stage biotechnology company focused on developing and preparing to commercialize therapies 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 and diabetes are being developed. PharmaCyte’s treatment for cancer involves encapsulating genetically modified live cells that convert an inactive chemotherapy drug into its active or “cancer-killing” form. These encapsulated live cells are placed as close to a cancerous tumor as possible. Once implanted in a patient, a chemotherapy drug, which needs to be activated in the body (ifosfamide), is then given intravenously at one-third the normal dose. The ifosfamide is carried by the circulatory system to where the encapsulated cells have been placed. When the ifosfamide, which is normally activated in the liver, comes in contact with the encapsulated live cells, activation of the chemotherapy drug takes place at the source of the cancer without any side effects from the chemotherapy. This “targeted chemotherapy” has proven remarkably effective and safe to use in past clinical trials.

In addition to developing a novel treatment for cancer, PharmaCyte is developing a treatment for Type 1 diabetes and Type 2 insulin-dependent 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.

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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