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PharmaCyte Biotech Successfully Completes Pyrogenicity Testing

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a biotechnology company focused on developing cellular therapies for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, announced today that it has successfully completed the crucial pyrogenicity testing that is required by the U.S. Food and Drug Administration (FDA) of the encapsulation material used to manufacture PharmaCyte's Cell-in-a-Box® capsules (CypCaps™). The capsules, which house live human cells, passed the test and are deemed non-pyrogenic.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said of the completed pyrogenicity testing, "While we never doubted that the capsules would be pyrogen free, we are very pleased that this vital FDA-required study has been successfully completed. We continue to remain centrally focused on submitting an Investigational New Drug application (IND) to the FDA. To that end, our team works every single day to complete the necessary items that will allow PharmaCyte to submit an IND for its planned Phase 2b clinical trial in locally advanced, inoperable pancreatic cancer. Meanwhile, as each test and item are completed, our team of experts and consultants is diligently compiling the data from these completed items and creating our IND package in real time."

All medical products that are delivered to the body have to be pyrogen free. Pyrogens are fever inducing substances that can cause side effects and influenza-like symptoms. Substances produced by bacteria (endotoxins) can be pyrogens, but other nonbacterial substances can be pyrogenic too.

The Cell-in-a-Box® encapsulation procedure uses starting materials that have been tested and shown to be endotoxin free. However, the encapsulation process and machinery used for production of PharmaCyte's CypCaps™ might potentially introduce nonbacterial pyrogens into the material used to encapsulate the human cells. The United States Pharmacopeia[1] as well as the FDA[2] require that advanced therapeutic medicinal products like CypCaps™ have to be tested for pyrogens.

In order to comply with these regulatory requirements, PharmaCyte requested Austrianova to produce a dedicated batch of empty cGMP capsules for pyrogenicity testing. It was an involved and time-consuming process to engineer empty cGMP capsules for the pyrogenicity testing. Once the empty capsules were manufactured, they were sent to Nelson Labs in Salt Lake City, Utah, for testing. A protocol had to be developed for the unique test material that would be used in rabbits. The capsules were extracted in saline at 50C for 72 hours and the extract was then injected into rabbits. This was done in order to determine if the injected matrix caused a fever. The results of the study have just been released. PharmaCyte can make the long-awaited announcement that the capsules passed the test and are deemed non-pyrogenic.

[1]*United States Pharmacopeia (USP), 2011*

[2]*U.S. Department of Health and Human Services Food and Drug Administration, Guidance for Industry Pyrogen and Endotoxins Testing, 2012*

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

About PharmaCyte Biotech

PharmaCyte Biotech, Inc. (PharmaCyte) 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 as 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.

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 because 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 due to the impact of numerous 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 at www.PharmaCyte.com. Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

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Dr. Gerald W. Crabtree
Investor Relations:
PharmaCyte Biotech, Inc.
Investor Relations Department
Telephone: 917.595.2856
Email: Info@PharmaCyte.com

Source: PharmaCyte Biotech, Inc.