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PharmaCyte Biotech Successfully Completes Another FDA Required Study Necessary for Submitting Investigational New Drug Application

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a clinical stage biotechnology company focused on developing targeted cellular therapies for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, today announced that it has successfully completed the comprehensive characterization of its proprietary cell clone known as 22P1G.

The 22P1G cells constitute the cells in the Master Cell Bank (MCB) that were prepared and tested by PharmaCyte's contractor, Eurofins Lancaster Laboratories. The cells from the MCB will serve as the active pharmaceutical ingredient (API) in the company's Cell-in-a Box® capsules that will be used (together with low doses of the cancer prodrug ifosfamide) for the treatment of locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC) in its planned clinical trial.

The comprehensive characterization studies include long-term stability of the cells, and stability of the potency of the cells as a therapeutic. All studies performed are required by the U.S. Food and Drug Administration (FDA).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, elaborated on the significance of the studies saying, "PharmaCyte is complying with all of the FDA guidelines and recommendations for all cell tests and other recent studies with the 22P1G cells. Successful completion of these studies was a pre-requisite for the approval by the FDA for us to conduct a clinical trial in patients with LAPC. Our treatment is primarily dependent upon genetically engineered live-human cells that produce a particularly potent cytochrome P450 enzyme that can activate the chemotherapy prodrug ifosfamide (clone 22P1G cells).

"With each individual batch, these cells must be stable for the long term, and the properties of the 22P1G cells must remain consistent from batch to batch. The newly completed studies provide evidence that both requirements have been met. Our pancreatic cancer treatment utilizes 22P1G cells that have been encapsulated using the Cell-in-a-Box® technology. For treatment of LAPC patients, the capsules containing the cells are implanted near the pancreatic tumor so that a high local concentration of the cancer-killing ifosfamide metabolite is produced near the tumor."

About PharmaCyte Biotech

PharmaCyte Biotech is a clinical stage 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 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, store and release insulin in response to the levels of blood sugar in the human body and/or beta islet cells. 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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Investor Relations:
PharmaCyte Biotech, Inc.
Dr. Gerald W. Crabtree, 917.595.2856
Investor Relations Department
Info@PharmaCyte.com

Source: PharmaCyte Biotech, Inc.