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PharmaCyte Biotech Reports Completion of Crucial FDA-Required Study for Pancreatic Cancer Trial

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 determined the modified site and chromosome location of the cytochrome P450-2B1 gene in the DNA of the genetically altered human cells known as 22P1G that will be encapsulated and used together with the cancer prodrug ifosfamide in PharmaCyte's upcoming clinical trial. The cytochrome P450-2B1 gene is responsible for producing the enzyme that activates the ifosfamide into its cancer-killing form. The "integration site" information from this study was another requirement requested by the FDA. The site of integration was to be defined and included in PharmaCyte's Investigational New Drug Application (IND) before the start of the clinical trial for the treatment of locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said, "This study answers one of the key questions that was raised in our pre-IND meeting with the FDA. It represents the culmination of a long, complicated and expensive series of experiments as well as interpretation of a plethora of data that was generated over the last 12 months and is congruent with earlier data that we generated. Without these findings, we would be unable to submit our IND to the FDA, so this completed study moves us a significant step closer to submitting our IND to the FDA."

The study was an exceedingly complicated one that involved the latest cutting-edge techniques such as Next Generation Sequencing (NGS) as well as more classical techniques of polymerase chain reaction (PCR) analysis and DNA sequencing. The comprehensive and voluminous set of data that was generated from these tests was subjected to a robust and multi-faceted analysis. In addition to providing a better characterization of the cells at the DNA level, this analysis has revealed that the cytochrome P450-2B1 expression construct is located on human chromosome 9 in PharmaCyte's 22P1G cell line. Additional analyses have revealed that the location of the construct is in a benign region of the human genome that should be "safe." This supports the previous conclusion that the 22P1G cells have a good safety profile.

The data obtained from the in-depth analyses also confirm data that has been previously announced by PharmaCyte that concerned enzymatic assays and Southern blotting analyses (a method used in molecular biology for detection of specific DNA sequence in DNA samples) of the 22P1G cells.

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. The cell lines being studied and developed are human liver cells, stem cells and 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 are designed to 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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