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PharmaCyte Biotech Announces Additional Quality Control Assay and Confirms Stability of CypCap Cells

LAS VEGAS--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (NASDAQ: PMCB), a biotechnology company focused on developing cellular therapies for cancer, diabetes and malignant ascites using its signature live-cell encapsulation technology, Cell-in-a-Box®, today announced the results of a study to determine whether a previous established quantitative real-time PCR (qRT-PCR) could be used as a quality control test for its CypCaps™ product candidate. The qRT-PCR was used to gain data from testing of syringes from clinical batches of PharmaCyte's cGMP production for its planned clinical trial in locally advanced, inoperable pancreatic cancer.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, commented on this new confirming assay, saying, "With the completion of this study, the Company has fulfilled one more important item from the long list of required U.S. Food and Drug Administration (FDA) tasks for our pancreatic cancer product candidate. We are particularly pleased that this independently performed qRT-PCR shows yet again the stability at the genetic level of the cytochrome P450 expressing cells which form the engine for our CypCaps clinical trial product. Additionally, we continue to make uninterrupted progress and remain steadfast in our efforts to resubmit an Investigational New Drug Application to the FDA and have our clinical hold lifted."

The study, performed by a third-party laboratory, confirmed that the qRT-PCR can be successfully implemented for testing, and it also confirmed the identity and stability of the cytochrome P450 expression construct in the cells used for the production of CypCaps both before and after encapsulation in the cGMP batches. The qRT-PCR will thus be used as a quality control (QC) release assay on future cGMP-grade clinical batches of CypCaps. The results obtained from the newly reported study also serve as additional evidence that the integrated cytochrome P450 construct is highly stable in the clinical cell line used for CypCaps.

PharmaCyte is at the tail end of its process of fulfilling the FDA's requests to enable the clinical hold to be lifted, having now successfully completed almost two dozen studies with only a few remaining to be completed. The Company expects to commence its two-phase pig study shortly, which is the last major study from the FDA.

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. is a biotechnology company developing cellular therapies for cancer, diabetes and malignant ascites based upon a proprietary cellulose-based live-cell encapsulation technology known as “Cell-in-a-Box®.” This technology is being used as a platform upon which therapies for several types of cancer, diabetes and malignant ascites 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 we believe results in little to no treatment related side effects.

PharmaCyte’s candidate 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. The encapsulation of the cell line will be done using the Cell-in-a-Box® technology. Once the encapsulated cells are implanted in a diabetic patient, we anticipate that they will function as a “bio-artificial pancreas” for purposes of insulin production.

PharmaCyte’s therapy for malignant ascites involves using the same encapsulated cells PharmaCyte employs for pancreatic cancer but placing the encapsulated cells in the peritoneal cavity of a patient and administering ifosfamide intravenously.

Safe Harbor

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that express the current beliefs and expectations of PharmaCyte’s management and Board of Directors. Any statements contained in this press release which do not describe historical facts are forward-looking statements subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. Factors that could affect our actual results include our ability to satisfactorily address the issues raised by the FDA in order to have the clinical hold on our IND removed, as well as such other factors that are included in the periodic reports on Form 10-K and Form 10-Q that we file with the U.S. Securities and Exchange Commission. These forward-looking statements are made only as of the date hereof, and we undertake no obligation to update or revise the forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

More information about PharmaCyte Biotech can be found at https://www.PharmaCyte.com.

Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

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