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PharmaCyte Biotech Successfully Completes 1 Year Stability Study

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 twelve-months product stability testing required by the U.S. Food and Drug Administration (FDA) for its CypCaps™ final clinical trial product. This product will be used in the company's planned clinical trial in locally advanced, inoperable pancreatic cancer upon the FDA lifting the clinical hold on PharmaCyte's Investigational New Drug Application (IND).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said of the completed twelve-month stability study, "We are pleased that our CypCaps™ product successfully completed all of the required stability tests and that the product has now shown itself to be stable and active after being stored for 1 year at -80°C. The study will continue in order to determine the maximum shelf life of the CypCaps™ product. It should be noted that this data is exceptional for a product of this kind."

As reported previously, the ongoing stability study is designed to determine the shelf life of the Cell-in-a-Box® encapsulated cell product, CypCaps™, stored frozen at -80°C. Upon analysis after 12 months in storage at -80°C, the unfrozen CypCaps™ product passed all of the specified tests, including cell viability, enzyme activity and cell potency as well as pH, label check, capsule appearance, and integrity. This twelve-month data, as well as all future longer-term time points of the shelf life analyses, such as the next time point to be evaluated after 18-months of storage at -80°C, will be reported to the FDA. This ongoing stability study was initiated prior to the submission of the company's IND to the FDA, and the information and data will form part of the package of information together with data from additional studies requested by the FDA.

In a survey of European biotech/biomedical companies developing advanced therapeutic medicinal products (i.e., products containing living cells like CypCaps™), shelf life issues were reported to be one of the major challenges that such products face (ten Ham et al., 2018, Molecular Therapy: Methods & Clinical Development vol. 11, pp121-130). Laboratory data on non-GMP produced encapsulated cells have suggested that the shelf life of Cell-in-a-Box products stored at -80°C is even longer than 1 year.

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 and diabetes 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 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 we believe 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. 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.

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 the management of PharmaCyte. Any statements contained herein that do not describe historical facts are forward-looking statements that are 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 raise the necessary capital to fund our operations and to find partners to supplement our capabilities and resources, 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 www.PharmaCyte.com. Information may also be obtained by contacting PharmaCyte’s Investor Relations Department.

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