

## PharmaCyte Biotech Successfully Completes 24-Month Stability Study of Its Clinical Trial Product Candidate

LAS VEGAS--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (NASDAQ: PMCB), a biotechnology company focused on developing cellular therapies for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box<sup>®</sup>, announced today that it has successfully completed a 24-month product stability study required by the U.S. Food and Drug Administration (FDA) for its clinical trial product candidate, CypCaps<sup>™</sup>. The significance of this timepoint is that CypCaps has now demonstrated that it has a shelf life of at least 24 months when stored at -80°C.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said of the completed 24-month stability study, "While we continue to establish a maximum shelf life for our clinical trial product candidate, CypCaps, reaching the 24-month timepoint is highly significant in allowing PharmaCyte to store a biologic at -80°C. We demonstrated that frozen CypCaps maintain their viability, enzymatic activity and cell potency after 2 years of storage at -80°C in a cryopreserved state. This is a major milestone not only for PharmaCyte but also for the cell therapy field."

After 24 months storage of the Cell-in-a-Box encapsulated cell product, CypCaps, at -80°C, the product was thawed and analyzed for cell viability, enzyme activity and cell potency as well as being examined for pH, label integrity, capsule appearance, capsule integrity and container closure integrity.

Notably, over the entire 24-month period, there was no significant change in the number and viability of the encapsulated cells, or, most importantly, in the biological activity that is key to activating the anti-cancer mechanism PharmaCyte uses for its cancer therapy. The successfully completed stability study was initiated prior to the submission of the company's IND to the FDA, and the information and data obtained from the study will form part of the updated package of information that will be provided to the FDA, together with data from additional studies requested by this regulatory agency.

This formal study, performed under GMP conditions, confirms previous laboratory data generated by PharmaCyte's partner, Austrianova, showing cell viability and activity of a similar Cell-in-a-Box cell encapsulation product upon storage in the frozen state for over 6 years.

This data is remarkable and stands in stark contrast with data obtained after cryopreservation of alginate encapsulated cells where one study showed viability after 2 weeks storage (*Nicola Cagol, Walter Bonani, Devid Maniglio, Claudio Migliaresi, Antonella Motta (2018) Effect of cryopreservation on cell-laden hydrogels: comparison of different* 

cryoprotectants. Tissue Eng. Part C Methods 24:20-31) and another using alginate encapsulated islets showed viability when thawed after 4 weeks storage in a frozen state (Greg G Kojayan, Antonio Flores, Shiri Li, Michael Alexander, and Jonathan RT Lakey (2019) Cryopreserved alginate-encapsulated islets can restore euglycemia in a diabetic animal model better than cryopreserved non-encapsulated islets. Cell Medicine 11: 1-6). Another study using cryopreserved cardiosphere-derived cells encapsulated in alginate-poly-L-lysine-alginate microcapsules showed viability of the cells after being revived 60 days after storage in a frozen state (Paz-Artigas L, Ziani K, Alcaine C, Báez-Díaz C, Blanco-Blázquez V, Pedraz JL, Ochoa I, Ciriza J. (2021) Benefits of cryopreservation as long-term storage method of encapsulated cardiosphere-derived cells for cardiac therapy: A biomechanical analysis. Int J. Pharm. 607:121014).

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: <a href="https://www.PharmaCyte.com/Cancer">https://www.PharmaCyte.com/Cancer</a>

## **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<sup>®</sup>." 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 function 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 <a href="www.PharmaCyte.com">www.PharmaCyte.com</a>. Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

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