

August 31, 2021



PharmaCyte Biotech Establishes 18-Month Shelf Life for Clinical Trial Product in Ongoing Stability Study

LAGUNA HILLS, Calif.--(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[®], announced today that its clinical trial product, CypCaps[™], remains stable and active at 18 months after completing the 18-month timepoint of ongoing product stability testing required by the U.S. Food and Drug Administration (FDA). This means that the product has a shelf life of at least 18 months when stored at -80°C. The next scheduled timepoint in the ongoing testing will be after 2 years of storage at -80°C.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said of the completed 18-month timepoint in its ongoing stability study, "We are pleased to announce these extended stability conditions, which will be included in our updated package of information that we provide to the FDA with the goal of lifting the clinical hold on our Investigational New Drug application (IND). This is an important development and enables simpler distribution and more flexibility at our clinical trial sites in the U.S. for our planned Phase 2b clinical trial in locally advanced, inoperable pancreatic cancer should the FDA grant us an open IND."

Analysis after 18 months in storage at -80°C, the unfrozen CypCaps product passed all the specified tests, including cell viability, enzyme activity, cell potency, pH, label check, capsule appearance and integrity. This ongoing stability study was initiated prior to the submission to the FDA of the Company's IND. The information and data from the stability study will form part of the updated package of information that PharmaCyte will provide to the FDA, together with data from additional studies requested by the FDA.

As noted in a recent review article in "Frontiers in Medicine" by Meneghel and colleagues, stable cryopreservation is a key element in the successful delivery of live cell-based therapies. *Meneghel J, Kilbride P and Morris GJ (2020) Cryopreservation as a Key Element in the Successful Delivery of Cell-Based Therapies—A Review. Front. Med. 7:592242. doi: 10.3389/fmed.2020.592242*

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 <https://PharmaCyte.com>
Information may also be obtained by contacting PharmaCyte’s Investor Relations Department.

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Investor Relations:

Dr. Gerald W. Crabtree

PharmaCyte Biotech, Inc.

Telephone: 917.595.2856

Email: InvestorRelations@PharmaCyte.com

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