

September 14, 2020



## PharmaCyte Biotech Successfully Completes Six-Month Stability Study

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a clinical-stage 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 the six-month product stability testing that is required by the U.S. Food and Drug Administration (FDA) for its clinical-trial ready product known as CypCaps<sup>™</sup>. This product will be used in the company's planned clinical trial in locally advanced, inoperable pancreatic cancer (LAPC) for which PharmaCyte submitted an Investigational New Drug application (IND) to the FDA in early September.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said of the completed six-month stability study, "Our IND submission is now with the FDA for review, but independent of the IND we are working on our ongoing storage stability study to determine the shelf life of the Cell-in-a-Box<sup>®</sup> encapsulated cell product. It will be kept stored frozen at -80°C throughout the entire duration of the stability study. The six-month time point of the study was recently reached, and we are pleased to report that CypCaps<sup>™</sup> has passed all of the FDA-required tests. With each successful time point reached, this means our final product has proven that it can remain functional when frozen and stored up to that time point.

"This is a continuation of ongoing 24-month stability study to demonstrate the shelf life of our final clinical trial product that the FDA requires for all medicinal products. These six-month data, as well as all future longer-term shelf life analyses, such as the next twelve months post-production shelf life evaluation, will be reported to the FDA but this information does not require PharmaCyte to modify its submitted IND."

ICH guidelines, as well as regulatory agencies around the world, including the FDA, require that shelf life data needs to be determined and provided for any new medicinal product. The functionality of cell-based therapies such as CypCaps<sup>™</sup>, as well as live vaccines etc., are particularly prone to loss of viability, and thus activity, during storage. This necessitates detailed shelf-life determination studies for such products.

A whole range of predefined and agreed tests have been performed on CypCaps<sup>™</sup> that were unfrozen after six months of storage at -80°C. These studies include determinations of the number of cells, cell viability, biological activity of the cells, integrity of the capsules, sterility and pH. It also includes verifying that the labels are still securely adhering to the frozen syringes and are still legible. These tests were performed either by Austrianova (cell count, biological activity of the cells, capsule integrity, label integrity) or by its affiliated subcontractor (sterility, pH measurement).

The recently reported Container Closure Integrity test that demonstrates that the syringes are properly sealed and that the contents of the syringes have not been contaminated is also formally part of the product stability testing. Thus, the CypCaps<sup>™</sup> product passed all of the

required tests at this six-month time point.

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. (PharmaCyte) 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 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 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. PharmaCyte is developing the use of genetically modified liver cells and stem cells, as well as beta islet cells, to treat diabetes. The encapsulation will be done using the Cell-in-a-Box<sup>®</sup> technology. Once the encapsulated cells are implanted in a diabetic patient, they will 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](http://www.PharmaCyte.com). Information may also be obtained by contacting PharmaCyte's Investor Relations

Department.

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**Dr. Gerald W. Crabtree**

**Investor Relations:**

PharmaCyte Biotech, Inc.

Investor Relations Department

Telephone: 917.595.2856

Email: [Info@PharmaCyte.com](mailto:Info@PharmaCyte.com)

Source: PharmaCyte Biotech, Inc.