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# PharmaCyte Biotech “Release Testing” Successful on All Completed Tests of Clinical Trial Product

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<sup>®</sup>, announced today an update on the completed tests that are part of the U.S. Food and Drug Administration (FDA) required “release testing” related to the company's first manufactured batch of its clinical trial product to be used in its planned Phase 2b clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

There are 10 total tests that make up the company’s “release testing.” To date, 5 of those 10 tests have been completed and all 5 have passed, including 4 of the 5 tests being conducted by third-party laboratories on the first manufactured batch of PharmaCyte’s clinical trial product.

PharmaCyte's partner, Austrianova Singapore (Austrianova), is conducting 5 of the tests, which are all related to the “functionality” of the encapsulated cells, while third-party laboratories are conducting the remaining 5 tests, which are all related to the “safety” of the company’s clinical trial product.

Among those successful tests was the “enzymatic activity” test that was performed by Austrianova. The last remaining test being conducted by a third-party laboratory is still in progress and is being conducted in the Netherlands by Eurofins.

PharmaCyte’s Chief Executive Officer, Kenneth L. Waggoner, said of the release testing, “We continue to be pleased that we’ve completed all of our manufacturing runs successfully and that we have a clinical trial product. Now, we follow that initial news with more good news that all of the release testing from the first successful manufacturing run carried out so far has been completed successfully.

“While the release testing is being conducted, we’re working to finalize the Protocol, the Investigator Brochure, the Pharmacy Manual and the Angiography Guidelines. We are also engaged in a selection process for a vendor to handle our clinical drug supply chain. All of these tasks should be complete by the time we receive the data from all of the release testing being conducted on the first and second manufacturing runs.

“After we receive all of the results from release testing, we will enter the data from those results into our Investigational New Drug application (IND) and then submit an entire package of information and supporting documents to the FDA for our planned Phase 2b clinical trial in LAPC.”

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®." 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® 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 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, including statements regarding the timing and commencement of our first Phase 2b clinical trial. 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 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 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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