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PharmaCyte Biotech Successfully Completes Container Closure Integrity Test

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 Container Closure Integrity (CCI) test that is required by the U.S. Food and Drug Administration (FDA) for its CypCaps™ product and has passed the FDA-required test. This is the final FDA-required test on the product that will be used in the company's planned clinical trial in locally advanced, inoperable pancreatic cancer.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said of the completed test, "It is with great enthusiasm that we announce our Cell-in-a-Box® encapsulated cell product CypCaps™ has passed the CCI test. This test is a component of the 24-month stability study. As with the test results we announced earlier this month, the CCI test is part of the ongoing study to determine the shelf life of the CypCaps™ final product that the FDA requires for all medical products. The data from the CCI test will be included in our IND. All future longer-term shelf life analyses, such as the next CCI test at the one-year post-production time period, will be reported to the FDA but is not required for PharmaCyte to submit its Investigational New Drug application (IND)."

As explained previously, regulatory agencies around the world, including the FDA, require a shelf-life determination for all medical products. Living products, like cell therapies such as CypCaps™, as well as live vaccines etc., are particularly sensitive and more prone to inactivation over time, so it is especially important to determine the shelf-life for PharmaCyte's clinical trial product.

The FDA specifically required a CCI test be run on PharmaCyte's clinical trial product and that the data from the CCI test be included in PharmaCyte's IND.

More can be read about the specifics of the CCI test in PharmaCyte's June 15, 2020 press release: https://pharmacyte.com/pharmacyte-biotech-successfully-accelerates-development-of-container-closure-integrity-test-for-pancreatic-cancer-clinical-trial-product/.

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 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. Information may also be obtained by contacting PharmaCyte’s Investor Relations Department.

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