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PharmaCyte Biotech Successfully Accelerates Development of Container Closure Integrity Test for Pancreatic Cancer 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®, today announced that it has successfully accelerated the development of its Container Closure Integrity (CCI) test– an essential component of the Stability Test required by the U.S. Food and Drug Administration (FDA).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, stated, "We are extremely pleased that the company we selected to develop our CCI test was not only successful in the development of the test, but that it was able to complete the development phase of the test much sooner than we anticipated given the test had to be developed from scratch because it is specific to our clinical trial product.

"There were three components to the development of our CCI test, and fortunately, each component was developed without a single setback. Now, we're in a position to run the CCI test according to the method developed."

The FDA specifically required a CCI test be run on pre-filled syringes containing 300 cellulose sulphate microcapsules in 2mls of freezing medium, and then the data from the CCI test be included in PharmaCyte's Investigational New Drug application (IND). Initially, PharmaCyte was prepared to submit the IND with the CCI test data following the IND submission. Because we envisioned the CCI test taking much longer to develop, we planned to use the data from the sterility test as a surrogate for the CCI test. However, use of a surrogate may no longer be required.

The first developmental phase of the CCI test was to develop a High Voltage Leak Detection (HVLD) program setup and feasibility study. The objective was to develop a preliminary leak test method with the capability of differentiation of the PharmaCyte syringe system with 5µm defects and those without 5µm defects. These parameters were utilized for performance qualification and functioned to verify the use of the PharmaCyte system with a HVLD instrument.

The second developmental phase of the CCI was to develop the method for such a HVLD system. The method development included using a PTI E-Scan HVLD leak test instrument with a sample set of laser-drilled defects (small manually created holes on the sides of several syringes) and use of syringes with no known defects at all. Certain parameters were used for optimization. The method was developed using PharmaCyte's filled syringes. A

representative placebo was also utilized. The final product was verified in development prior to the validation with the optimized parameters.

The third developmental phase was to validate a leak test method using HVLD technology. All work was completed using a PTI E-Scan HVLD leak test instrument. Validation included three test series across multiple days and operators.

Now all that remains is the development of a protocol by which frozen samples of PharmaCyte's clinical trial product will be tested employing the validated high voltage method for PharmaCyte's syringe system for container closure integrity over time. That work is underway.

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. In addition, PharmaCyte is developing and preparing to obtain approval from the FDA to commercialize a COVID-19 diagnostic kit to meet a critical unmet medical need for such kits during the current pandemic.

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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