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PharmaCyte Biotech Completes Final cGMP Audit of Manufacturing Facility 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 cGMP Validation, the company's cGMP consultant, has completed its post manufacturing audit of the manufacturing facility in Thailand and that the facility has successfully passed the audit. This facility is where PharmaCyte's clinical trial product was manufactured by the company's partner, Austrianova Singapore (Austrianova). PharmaCyte can now import its clinical trial product to the company's supply chain vendor in the United States (U.S.) who will then store the product at -80C until it is needed at clinical trial sites.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, stated, "We're exceedingly pleased that the time consuming and laborious work to conduct the cGMP audit of the manufacturing facility that produced our clinical trial product to cGMP standards has now passed the audit. This is the second independent audit of Austrianova. The first was performed by a different audit company before manufacturing commenced, and the current, just completed audit, was performed after manufacturing concluded. The audit process was particularly laborious and time intensive because of the complexity and length of the manufacturing process using Cell-in-a-Box® technology to manufacture our clinical trial product. We would like to express our appreciation for all of the efforts made by the teams at Austrianova and cGMP Validation to complete the audit in these difficult times working together half-way around the world."

Austrianova's Chief Executive Officer, Brian Salmons, commented, "We, too, are pleased that PharmaCyte has successfully completed the comprehensive audit of our facility, processes and manufacturing procedures and records. In total, almost 5000 documents have been generated, reviewed and analysed related to the manufacturing of PharmaCyte's product using the Cell-in-a-Box® technology. The current audit involved a team of 4 experts from Austrianova and 2 experts from cGMP Validation. We are happy that two independent audit firm have confirmed that Austrianova is operating according to U.S. FDA standards"

A cGMP manufacturing facility audit involves innumerable components to evaluate, review and assess according to cGMP standards. Among others, cGMP Validation had to evaluate the facilities, equipment and laboratory in Thailand. It also had to review all pertinent documents that support cGMP and PharmaCyte's specifications. Assessment of Austrianova's Quality Management Systems, including all internal SOPs and associated cGMP documents was required. The same is true for Austrianova's CAPA programs (Corrective Action/ Preventive Action). Review validation of manufacturing equipment, product process, and equipment cleaning also needed to be accomplished. Review of method validation (analytical and microbiological) was also required. And an evaluation of

data integrity related to the manufacturing runs took place.

There was a total of 35 items that made up the establishment and maintenance of a U.S. Food and Drug Administration (FDA) required Quality Program associated with the Austrianova manufacturing facility.

Important specific items for review during this audit consisted of the following: (i) HVAC and facility maintenance records; (ii) environmental data and trends; (iii) calibration records; (iv) equipment/utility/process Validation Change Control records; (v) equipment/utility/process Revalidations records; (vi) document control; (vii) SOP updates; (viii) any changes to processing batch records; (ix) trends of batch record data; (x) stability data; (xi) retained samples; (xii) investigations and conclusions; (xiii) laboratory equipment validations; (xiv) any changes and subsequent validations for analytical methods validation; (xv) latest annual cleaning records and (xvi) employee training records and education.

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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