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PharmaCyte Biotech Conducting Final Audit of Manufacturing Facility after Batch Records Deemed cGMP Compliant

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 GMP consultant, is conducting its final audit of the manufacturing facility in Thailand where PharmaCyte's clinical trial product was produced by PharmaCyte's partner, Austrianova Singapore (Austrianova). When the audit is completed, cGMP Validation will give PharmaCyte approval to import the clinical trial product to the company's supply chain vendor in the United States (U.S.) who will store the product at -80C until it is needed.

In addition, Austrianova and cGMP Validation have now completed their work together to achieve what has been deemed cGMP compliant batch records for the two manufacturing runs successfully produced by Austrianova. Both worked closely together to revise the batch records that were generated during the two manufacturing runs that produced PharmaCyte's clinical trial product for its planned Phase 2b clinical trial in locally advanced, inoperable pancreatic cancer (LAPC). A batch record is a detailed written document of a manufactured batch of product, prepared during a pharmaceutical manufacturing process. A batch record contains actual data and the step by step process for manufacturing each batch. The completed manufacturing batch records are proof that the two batches were properly made and checked by quality control personnel at Austrianova according to cGMP standards. This was necessary so that the batches comply with the standards required by the U.S. Food and Drug Administration (FDA) for a batch record for each manufacturing run.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said, "We continue to work through a checklist of items that are necessary to submit an acceptable Investigational New Drug application (IND) to the FDA. The work that cGMP Validation and Austrianova are currently performing to audit the manufacturing facility in Thailand and the work they have completed working together to make certain the batch records meet the cGMP requirements for manufacturing a clinical trial product was and continues to be incredibly detailed and must continue to follow strict FDA guidelines.

"We are extremely pleased that the final audit of the manufacturing facility is underway and that our batch records from the two successful manufacturing runs meet all FDA cGMP requirements as the product is not considered a cGMP product unless it meets these stringent standards."

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 U.S. 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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