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# PharmaCyte Biotech Successfully Develops “Change History” for its Clinical Trial Product for Pancreatic Cancer

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 completed development of the “change history” information and data for CypCaps™ (2nd generation product) compared to CapCell™ (1st generation product). The history of the changes to the manufacturing of the two generations of product is a critical component of PharmaCyte’s Investigational New Drug application (IND) and is specifically required by the U.S. Food and Drug Administration (FDA).

PharmaCyte’s Chief Executive Officer, Kenneth L. Waggoner, stated, “We are very pleased that our partner Austrianova developed the needed information and data to be in a position to satisfy our cGMP consultant and our regulatory consultant that the information and supporting data should be sufficient to meet the FDA comparability requirements of the two generations of encapsulated live human cells.

“The first generation of product was referred to as “CapCell™”, and the current generation of product is referred to as “CypCaps™.” Although the cellulose material is basically the same, a material of improved quality is used in the 2nd generation product. The differences relate to control of impurities with heavy metal content and microbial and endotoxin levels being below the limits in the relevant literature for powdered cellulose. In addition, the production process for the cellulose is more closely controlled in the 2nd generation product. The original cell line used is also now better characterized at the genetic level. Lastly, the encapsulated cells undergo a maturation process in the 2nd generation product and are stored frozen for a longer shelf life.

“In short, while both generations of product use the identical cell line, the CypCaps™ have improved quality and control of the cells, improved encapsulation material reproducibility, better controlled cell filling and a much-improved shelf life, resulting in a more robust product overall.”

The FDA requires that all relevant information and data from different generations of the same manufactured medicinal product be compared to one another to ensure that the original manufactured product is essentially the same as the current one. There can be improvements to the product, but to use the data from the two clinical trials in the 1990s to support PharmaCyte’s Phase 2b clinical trial, it was imperative to develop information and data to support that the two generations of the products are essentially the same – the only difference being improvement to the overall product using the same manufacturing process.

Austrianova also had to gather the data for the release specifications for each generation of

encapsulated cells and explain why changes were made and how the changes made for an improved product using the same manufacturing process. Information and data about the capsule maturation and storage were also developed.

In addition, the quality control release assay information and supporting data had to be assembled. This involved capsule diameter; viability of encapsulated cells; sterility; pyrogenicity; potency; cell identity; endotoxins; enzymatic activity; capsule count; label check; and pH.

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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