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PharmaCyte Biotech Provides IND Submission Update for Pancreatic Cancer Clinical Trial

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 is closing the gap in completing its Investigational New Drug application (IND) for its planned clinical trial in locally advanced, inoperable, pancreatic cancer (LAPC).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, stated, "We are pleased to report that the major challenges we faced in completing the IND have now been overcome. The remaining work no longer involves research and development or manufacturing. The remaining work now resides with our consultants to complete the documents required for the IND submission."

The Stability Study tests, which include the Container Closure Integrity test, are underway. These are the tests for the first "time point" in the two-year Stability Study. Successful data from these tests are required by the U.S. Food and Drug Administration (FDA) and will be incorporated into the IND.

Most of the remaining work is being handled by PharmaCyte's consultants. Set forth below is a list of the major items to be finalized by PharmaCyte and its consultants before PharmaCyte submits the IND to the FDA.

- Trial Protocol
- Investigator's Brochure
- Environmental Analysis
- General Investigation Plan
- Introduction Summary
- Nonclinical Overview
- Clinical Overview
- Nonclinical Written and Tabulated Summaries
- Drug Master File
- Pharmacy Manual
- Informed Consent
- Study Reports and related information of prior clinical studies pertinent to LAPC
- Regulatory Publishing of the IND and supporting documents

While this is not a complete list of all of the remaining tasks, it identifies the critical ones. However, there are no further pre-clinical tests remaining to commence before submitting the IND to the FDA.

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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