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# PharmaCyte Biotech Successfully Completes Multiple Course Ifosfamide Study

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- [PharmaCyte Biotech, Inc.](#) (OTCQB: PMCB), a clinical stage biotechnology company focused on developing targeted cellular therapies for cancer and diabetes using its signature [live-cell encapsulation technology, Cell-in-a-Box®](#), today announced that it has successfully completed a “multiple course ifosfamide study” required by the U.S. Food and Drug Administration (FDA). In the two earlier clinical trials using PharmaCyte’s encapsulation technology, Cell-in-a-Box® plus low doses of ifosfamide, only two courses of ifosfamide treatment were given to the patients.

As part of PharmaCyte’s Investigational New Drug Application (IND), the FDA required PharmaCyte to provide data showing that the encapsulated cells PharmaCyte plans to use for its clinical trial in patients with locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC) are still alive and capable of converting the prodrug ifosfamide to its cancer killing form after multiple courses of ifosfamide are administered.

To provide the information required by the FDA, a series of in vitro experiments were performed with unfrozen encapsulated ifosfamide-activating cells in culture that were treated with successive courses of ifosfamide over many days. This extensive testing that was done to demonstrate the ifosfamide activating cells inside the Cell-in-a-Box® capsules can withstand multiple courses of ifosfamide administration has now been completed. The results show that the cells continue to activate ifosfamide to its cancer killing metabolite without themselves being damaged.

PharmaCyte’s Chief Executive Officer, Kenneth L. Waggoner, explained the significance of the successful study saying, “PharmaCyte’s treatment for LAPC utilizes cells that produce a particularly potent cytochrome P450 enzyme that is able to activate ifosfamide. These cells are encapsulated in the Cell-in-a-Box® technology, and the capsules are implanted near the cancerous tumor so that a high local concentration of the cancer killing, short-lived ifosfamide metabolite is produced near the tumor. Unlike the earlier two clinical trials, in our upcoming trial using the same cell-based therapy, we will be giving multiple doses of ifosfamide. We are extremely pleased that the final data from this study is positive and allows us to continue our forward momentum to filing our IND.”

Ifosfamide is a chemotherapeutic agent that is routinely used to treat a variety of cancers, including testicular cancer and non-Hodgkin’s lymphoma. Because ifosfamide is a prodrug, by itself it is not toxic to cancer cells. Ifosfamide must be activated by cytochrome P450 enzymes such as those found in the cells to be used in into a short-lived intermediate form that can enter tumor cells and kill them. Since the capsules are filled with ifosfamide-activating cells that are alive but are no longer dividing and the cell-killing effect is limited to cells that can multiply (such as those growing in a cancerous tumor); this forms the basis for

the tumor selectivity of ifosfamide in PharmaCyte's upcoming trial in patients with LAPC.

## **About PharmaCyte Biotech**

PharmaCyte Biotech is a clinical stage 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.

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 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, store and release insulin in response to the levels of blood sugar in the human body and/or beta islet cells. 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](http://www.PharmaCyte.com). Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

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