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# PharmaCyte Biotech Successfully Completes Final Pre-Production Run of Pancreatic Cancer Product

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 its partner, Austrianova, has successfully performed an additional pre-production “engineering run” using the Cell-in-a-Box® encapsulated cells that will be used, in combination with low doses of the cancer prodrug ifosfamide, for the treatment of locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC).

On the advice of PharmaCyte’s Chief Scientific Officer and Austrianova, who will be performing the full production process of PharmaCyte’s clinical trial material, it was decided that the first production run would be deemed an engineering/pre-production run to be conducted before the production run to produce clinical trial material begins.

PharmaCyte’s Chief Executive Officer, Kenneth L. Waggoner, said, “We are happy to report that the encapsulation portion of the process during the pre-production run went flawlessly. Our decision has proven to be the correct course of action. We have much more information on how the cells from the Master Cell Bank (MCB) perform during and after encapsulation. The experience we have gained allowed Austrianova to make minor, but important, changes to the cell culture portion of the full production process. Completing the full production process and testing the final product now are the major items that remain to be accomplished before submitting our IND to the FDA.”

The full production process consists of several steps with the most important being (i) the encapsulation process and (ii) the subsequent culturing of the encapsulated cells.

PharmaCyte’s Cell-in-a-Box® technology, with the live cells inside, must be placed in a “culture bath” long enough for the capsules to become filled with about 10,000 living cells that stop dividing upon contact with neighboring cells. If the capsules contained dividing cells, those cells would be killed (and rendered useless for cancer therapy) within the capsules when the ifosfamide prodrug was administered.

The decision to regard the run as an engineering run before the final production run occurs resulted, partly, due to learning that the cells from the MCB produced by Eurofins show slightly altered growth properties when compared to the cells that were previously tested and then used to prepare the MCB. This finding is not unusual when a new cell bank is established. However, since any alterations in the growth characteristics of the cells from the MCB that were used for the current encapsulation run might impinge on aspects of the overall production process, to have any anomalies well characterized and in line with regulatory guidelines, this additional engineering run was performed.

The knowledge gained from the two engineering runs should allow for the final production run to produce clinical trial material to begin. Austrianova completed the entire production process a few weeks ago and since then has successfully filled syringes with capsules that were produced during this pre-production run. This process was carried out to mimic what will be done in the final production run from encapsulation to preparing for direct shipment of PharmaCyte's live-cell product to clinical trial study sites.

## **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<sup>®</sup>." 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 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, store and release insulin in response to the levels of blood sugar in the human body. PharmaCyte is exploring the use of genetically modified liver cells, stem cells and/or beta islet cells. The encapsulation will be done using the Cell-in-a-Box<sup>®</sup> 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

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