

PharmaCyte Biotech Successfully Completes Comparative Analysis of Methods for Measuring Viability of Encapsulated Cells

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 study to determine the best assay method for the accurate determination of the number of viable encapsulated cells at any given time inside PharmaCyte's Cell-in-a Box® capsules, which will be used for the treatment of locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC).

The decision on which viability assay to use is an important component required for the filing of PharmaCyte's Investigational New Drug Application (IND) with the U.S. Food and Drug Administration (FDA), since the viable cell assay is needed to show how many living cells are in the capsules at any given moment. This is a parameter that influences the biological activity of PharmaCyte's Cell-in-a-Box® encapsulated cell product.

This particular study compared three different methods for determining the number of viable cells in the capsules as well as the growth rate of the cells within the capsules. Although the rate of growth has already been fixed as part of the production process (and is not affected by this study), the new data revealed that only one of the tested methods can accurately estimate the number of cells within a capsule, particularly when the capsules are populated at high cell densities as they will be for use in PharmaCyte's clinical trial in patients with LAPC. Therefore, this study provides the justification for the use of the most accurate and sensitive assay chosen by this study, which will also be used for quality control of the product release for the upcoming planned clinical trial for LAPC.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, explained the significance of the study saying, "The cells that are encapsulated using the Cell-in-a-Box® technology are the engine for the final product in that they activate the chemotherapeutic agent ifosfamide at the site of the tumor in the pancreatic cancer patient. This study is important since it shows we now have at our disposal the best method to determine the actual number of living cells in the capsules.

"The data from this study is another key piece of information required for PharmaCyte to comply with FDA guidelines and recommendations for our planned, upcoming clinical trial in patients with LAPC. This viability information must be reliable; therefore, it is also valuable for ensuring good quality control of our final product. In other words, using the chosen viability measuring method will help us ensure that the Cell-in-a-Box® encapsulated product is reproducible from batch to batch. This is an essential requirement for any medicinal

product.”

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. The cell lines being studied and developed are human liver cells, stem cells and 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 are designed to 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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