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PharmaCyte Biotech Successfully Completes Another Study on the Encapsulated Cells Used in Its Pancreatic Cancer Therapy

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 on the stability after “hand thawing” syringes of 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). The data obtained from this “hand thawing” study is required by the U.S. Food and Drug Administration (FDA).

The filing of an Investigational New Drug Application (IND) requires that the clinical product, as well as the product’s use, should be well characterised. PharmaCyte’s Cell-in-a-Box® is a cutting edge Advanced Therapy Medicinal Product (ATMP). Therefore, numerous studies are needed since such a product has never been tested before in the United States. The laboratory scale “thawing” study previously conducted (<http://pharmacYTE.com/pharmacYTE-announces-successful-completion-6-month-stability-study-encapsulated-cells-clinical-trial/>) determined how long the once-frozen Cell-in-a-Box® encapsulated cells are still fit for use after thawing, as would occur in a clinical setting before the Cell-in-a-Box® capsules are implanted into a patient with LAPC. That study defined one of the important parameters for the upcoming planned clinical trial for LAPC.

At individual study sites, the frozen cells in the Cell-in-a-Box® capsules within syringes will be hand-thawed and then kept at room temperature until they are implanted into a patient with LAPC. The results of the “hand thawing” study announced today show that the viability of the cells remains essentially the same for at least 30 minutes at room temperature. This serves to define the time that the interventional radiologist has to implant the Cell-in-a-Box® capsules after thawing to ensure cellular viability within the patient.

PharmaCyte’s Chief Executive Officer, Kenneth L. Waggoner, explained the significance of the study saying, “This is yet another important study that PharmaCyte has completed to comply with the FDA’s requirements for our planned, upcoming clinical trial in LAPC. The Cell-in-a-Box® encapsulated cells are in a frozen state before they are administered to the patient. This study was designed to determine how long after unfreezing the Cell-in-a-Box® encapsulated cells can they be held at room temperature before being introduced into the patient without losing their effectiveness.

“This is important since the treatment depends on the viability of our genetically engineered

live human cells in order to produce the cytochrome P450 enzyme for the activation of the chemotherapy prodrug ifosfamide. The study's goal was to determine how long the cells remained viable at room temperature after thawing; thus, mimicking how long the clinicians and interventional radiologists will have to administer the capsules to the patient in the hospital. The newly completed studies show how long that Cell-in-a-Box[®] encapsulated cells can be kept at room temperature for optimal activity."

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. Information may also be obtained by contacting PharmaCyte's Investor Relations

Department.

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