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PharmaCyte Announces Successful Completion of 6-Month Stability Study on Encapsulated Cells for Clinical Trial

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 6-month study on storage of the frozen encapsulated cells necessary for the determination of an “initial shelf life” has been successfully completed by Austrianova. This work involved the removal of samples of encapsulated cells from -80° Celsius (C) storage at various intervals up to six months, thawing the encapsulated cells and testing them for various functional parameters as well as for sterility.

Regulatory agencies, including the U.S. Food and Drug Administration (FDA), require that studies be conducted to determine an initial shelf life for a medicinal product before an advanced phase clinical trial can begin. This shelf life can then be extended with further testing as the product is being used in the clinical trial. Austrianova Singapore already has data demonstrating storage life of frozen encapsulated cells for over six years; however, these studies were done with a slightly different cell line than the cell line that will be used for PharmaCyte’s planned clinical trial. The current completed study uses the Research Bank of cells that will be used in the final product for PharmaCyte’s trial and from which Eurofins has already generated PharmaCyte’s Master Cell Bank.

The stability test results show that there are no significant changes in the viability or the enzymatic activity of the cells upon thawing after a 6-month storage period at -80°C. These results will allow an initial shelf life of six months to be set for the product; this will be extended as the product is tested further.

PharmaCyte’s Chief Executive Officer, Kenneth L. Waggoner, stated, “We are pleased with this significant result which will enable us to apply to the FDA for an initial shelf life of six months. This study, one of many being performed for us by Austrianova, is an essential part of the Investigational New Drug Application (IND) that we will be submitting to the FDA.”

PharmaCyte is working on an IND to submit to the FDA so that it can begin a clinical trial involving locally advanced, inoperable, non-metastatic pancreatic cancer and expects to submit its IND later this year.

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 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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