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PharmaCyte Biotech Closer to Submitting IND by Successfully Completing Encapsulation of Second Manufacturing Run of Clinical Trial Product

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a biotechnology company focused on developing cellular therapies for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, is closer to submitting an Investigational New Drug application (IND) to the U.S. Food & Drug Administration (FDA). PharmaCyte announced today that its partner, Austrianova Singapore (Austrianova), has successfully completed encapsulation of the cells from PharmaCyte's Master Cell Bank (MCB) in the second of two staggered and back-to-back manufacturing runs for the production of PharmaCyte's clinical trial product. This product will be used for PharmaCyte's planned clinical trial in patients with locally advanced, inoperable pancreatic cancer (LAPC).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, commented, "The encapsulation process was performed last week at Austrianova's manufacturing facility in Thailand. After reviewing the first pictures of the encapsulated cells, we're confident that this manufacturing run is progressing as well as our first successful manufacturing run.

"We are anxiously awaiting the completion of the second of the two back-to-back manufacturing runs and the results from the FDA required testing on each of those runs. Once the information from that testing is available, it will be incorporated into our Investigational New Drug application (IND) for submission to the FDA."

Most of the work needed for PharmaCyte to submit an IND to the FDA has been completed. The rate limiting factor is and always has been for Austrianova to complete successfully two back-to-back manufacturing runs. During PharmaCyte's recent shareholder update call, the company reported on Austrianova's work to encapsulate successfully PharmaCyte's genetically modified human cells that will be used to treat patients suffering from LAPC.

After months of extensive research and development (R&D) by a team of experts from Austrianova and PharmaCyte, a total of eight different changes were made to the manufacturing process. It was not until the eighth and final change was made that the encapsulated cells grew as well in Austrianova's manufacturing facility in Thailand as they grew at Austrianova's R&D facility in Singapore.

Once the recently encapsulated cells in this second of two manufacturing runs have completely filled the capsules, they will be placed into PharmaCyte's clinical trial syringes and then frozen. A representative sample of those syringes will be thawed and undergo the FDA required "release testing." All "release testing" related to safety of the encapsulated cells is being outsourced by PharmaCyte to independent third-party laboratories in Europe.

All “release testing” related to functionality of the encapsulated cells is being handled by Austrianova at its GMP facility in Thailand.

To learn more about PharmaCyte’s pancreatic cancer treatment and how it works inside the body to treat locally advanced inoperable pancreatic cancer, the company encourages you to watch its documentary video complete with medical animations at: https://www.PharmaCyte.com/Cancer

About PharmaCyte Biotech

PharmaCyte Biotech, Inc. (PharmaCyte) is a 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 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 and release insulin in response to the levels of blood sugar in the human body. PharmaCyte is developing the use of genetically modified liver cells and stem cells, as well as beta islet cells, to treat diabetes. 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 may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that express the current beliefs and expectations of the management of PharmaCyte, including statements regarding the timing and commencement of our first Phase 2b clinical trial. Any statements contained herein that do not describe historical facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results, performance and achievements to differ materially from those discussed in such forward-looking statements. Factors that could affect our actual results are included in the periodic reports on Form 10-K and Form 10-Q that we file with the U.S. Securities and Exchange Commission. These forward-looking statements are made only as of the date hereof, and we undertake no obligation to update or revise the forward-looking statements, except as otherwise required by law, whether as a result of new information, future events or otherwise.

More information about PharmaCyte can be found at www.PharmaCyte.com. Information

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

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