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PharmaCyte Biotech Receives Certificates of Analysis and Batch Records for its Clinical Trial Product in Pancreatic Cancer

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®, announced today that it has received the Certificates of Analysis and the records from both batches of its clinical trial product manufactured by Austrianova Singapore (Austrianova). As previously reported, both batches of the company's clinical trial product have undergone and passed all of the necessary "release tests" required by the U.S. Food and Drug Administration (FDA).

PharmaCyte has engaged cGMP Validation to review the batch records and the Certificates of Analysis to ensure that they are complete and that they comply with FDA requirements. This is a significant milestone in preparing the documentation for the Investigational New Drug application (IND) PharmaCyte plans to submit to the FDA to commence a Phase 2b clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

PharmaCyte is also working with Facet Life Sciences (Facet), its experienced regulatory and development services organization, to prepare and submit the IND to the FDA. Facet will now begin work with cGMP Validation to populate those modules of the IND that provide detailed information on the release testing and how the clinical trial product was manufactured and tested. This process involves a complex analysis of hundreds of pages of detailed technical information related to the manufacturing and testing of PharmaCyte's clinical trial product.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said, "We are pleased to have received the Certificates of Analysis and now have access to the batch records from both manufacturing runs. This is a significant step forward. We have been waiting on the Certificates of Analysis to commission important next steps in order to complete the IND and related matters. We now have certification from Austrianova that our product has met the required release testing to demonstrate that our clinical trial product "functions" as it should and is "safe" to use in an FDA clinical trial

"In the coming days, there will be considerable work between our team and Austrianova to make sure everything we have received from Austrianova is cGMP compliant and comports with FDA regulations. Facet will now take the lead, working with our team, to complete the IND."

To learn more about PharmaCyte's pancreatic cancer treatment and how it works inside the body to treat locally advanced inoperable pancreatic cancer, we encourage you to watch the company's 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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