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# PharmaCyte Biotech Advances Manufacturing Process for Clinical Trial in Pancreatic Cancer

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LAGUNA HILLS, Calif.--([BUSINESS WIRE](#))--[PharmaCyte Biotech, Inc.](#) (OTCQB: PMCB), a 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 advances have been completed in the manufacturing process for the clinical trial product that will be used in PharmaCyte's planned clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

Since PharmaCyte's last press release describing the manufacturing process for its clinical trial product and the testing of that product, the data from the manufacturing process has been reviewed, analyzed and discussed in great detail among PharmaCyte's management team, including the leader of its clinical development program in pancreatic cancer and designated Principal Investigator (PI) for the LAPC trial, Prof. Manuel Hidalgo of the Harvard Medical School, Austrianova's management team (the manufacturer of the clinical trial product), cGMP Validation (PharmaCyte's cGMP expert consulting firm), Eurofins Lancaster Laboratories (who produced the cells for PharmaCyte's Master Cell Bank) and several consulting cellular biologists.

The data obtained to date from the encapsulation parameters of the manufacturing process itself indicate that the encapsulation portion of the process is fault free and reproducible, which is a fundamental requirement of the FDA.

On the advice of PharmaCyte's cGMP expert, the company plans to conduct two additional and staggered manufacturing runs in order to maximize the chances for a successful IND submission given the novelty and complexity of the entire process. In the time since the last manufacturing run, which we reported on in January of this year, those involved with the manufacturing process have been concentrating on changes that can be made to improve the process. We believe that these changes will improve the cGMP manufacturing process to the point that the entire process can be shown to be consistently reproducible and robust as required by the FDA, and to ensure that the end-products of these manufacturing runs will convert the cancer prodrug ifosfamide into its cancer-killing form as well as they should.

This intensive effort has involved several independent tests by Austrianova and Eurofins. The results of these tests strongly indicate that, after the suggested changes are implemented, positive results should be obtained. When the changes are made to the cGMP manufacturing process, they should significantly improve the growth of the cells obtained from the Master Cell Bank both before and after encapsulation takes place. PharmaCyte and Austrianova and its team of consultants are in the final stages of optimizing this aspect of the

manufacturing process.

Meanwhile, PharmaCyte's clinical development program in pancreatic cancer is progressing. As explained by Prof. Hidalgo, "PharmaCyte has a strong clinical trial program for pancreatic cancer. The trial design has been thoroughly vetted by a team of the best pancreatic cancer specialists in the country. I continue to lead PharmaCyte's program in pancreatic cancer, and I am eager to get underway as its PI for the LAPC trial. Members of PharmaCyte's team are working on various aspects of implementing the program. I remain excited about the potential that PharmaCyte's technology can offer patients who are suffering from LAPC and am looking forward to what a successful trial may mean for the way some types of solid cancerous tumors are treated in the future."

### **About PharmaCyte Biotech**

PharmaCyte Biotech 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<sup>®</sup>." 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 reportedly 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 are human liver cells, stem cells and beta islet cells. The encapsulation will be done using the Cell-in-a-Box<sup>®</sup> 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 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 Biotech, 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 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 Biotech can be found at [www.PharmaCyte.com](http://www.PharmaCyte.com). Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

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