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PharmaCyte Biotech Completes Report of FDA Required Study Assessing Safety of Placement of Its Pancreatic Cancer Product

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 U.S. Food and Drug Administration (FDA) required formal report on the safety studies conducted by Bavarian Nordic using a pig model that were undertaken before the first clinical trial in humans using cellulose-based capsules that contain live genetically altered cells which activate the anticancer prodrug ifosfamide. The voluminous information contained in the formal report is another complicated Investigational New Drug Application (IND) component requested by the FDA to be included in the IND before the start of the clinical trial for the treatment of locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC).

A formal study report, including all the data from the previously performed porcine animal studies, has been completed and independently reviewed and verified. The original data was published in part in the journal *Pancreatology,* but the confines of that scientific publication did not allow for the complete volume of data to be included in the journal article, necessitating several components of the studies to be woven together in a formal study report according to FDA guidelines. The original data was compiled and independently reviewed by Facet Life Sciences with the support of original members of the team that performed the porcine experiments, including Prof. Matthias Löhr who was the Principal Investigator for the first two pancreatic cancer trials with what has evolved into PharmaCyte's current treatment for pancreatic cancer. The final study report has now been signed off on by two members of the original team, Prof. Udo Losert and Prof. Walter H. Günzburg, and will be submitted to the FDA as part of the IND dossier required for approval for the commencement of PharmaCyte's planned clinical trial in LAPC.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said, "These large animal studies, which had to be retrieved from locations in several countries in Europe, demonstrate the safety of delivering capsules to the blood vessels (vasculature) leading to the pancreas in pigs and are supported by the initial clinical trial data generated to date, primarily from trials in Germany. The formal study report allows us to submit the complete set of data in the appropriate fashion to the FDA as part of our IND submission for our upcoming LAPC trial in the U.S."

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 cell lines being studied and developed are human liver cells, stem cells and 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 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. Information may also be obtained by contacting PharmaCyte’s Investor Relations Department.

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