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PharmaCyte Biotech Announces Submission of Drug Master File to FDA for Company's Pancreatic Cancer Therapy

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 its partner, Austrianova, has submitted a Drug Master File (DMF) to the U.S. Food and Drug Administration (FDA). The DMF provides all confidential and detailed information covering the production of the CypCaps™ final product, which was produced by Austrianova and will be used in PharmaCyte's planned clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said, "We've reached an exciting milestone at PharmaCyte that has us on the precipice of reaching our long-awaited goal of submitting an Investigational New Drug Application (IND). We're elated to announce that our partner, Austrianova, submitted a DMF with the FDA for the production of our Cell-in-a-Box® encapsulated cell product CypCaps™. This DMF is an important and significant event since it is the last prerequisite for the formal FDA application process. It will support and now facilitate the submission of our IND."

Austrianova's Chief Technical Officer, Walter H. Gunzburg stated, "The DMF filing is a key event for both PharmaCyte and Austrianova since it will provide the basis for many Cell-in-a-Box® products in addition to CypCaps™. The DMF is by its nature a comprehensive document compiled from many months of in-house work and past historical data and was compiled with the support and advice of an external consultant."

A DMF is submitted to the FDA to provide detailed information about facilities, processes and materials used in the manufacturing, processing and packaging of human drugs and biologics. It is a prerequisite to securing approval and commercialization and ensures confidentiality of proprietary information related to the Active Pharmaceutical Ingredient (API). The information contained in a DMF is used to support, among other applications, an IND.

The DMF requirements are complex and specific, encompassing every detail involved with the manufacture of the API – from raw materials to analytical methods, process development and optimization. The scrutiny goes all the way back to the starting materials used in the API.

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 a human liver 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 also considering the use of genetically modified stem cells to treat diabetes. The cell encapsulation will be done using the Cell-in-a-Box® technology. Once the encapsulated cells are implanted in a diabetic patient, we anticipate that they will function as a "bio-artificial pancreas" for purposes of insulin production. Until the FDA allows us to commence the clinical trial described in our IND involving LPAC, we are not spending any further resources developing this program.

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 the timing and commencement of our planned Phase 2b clinical trial in LAPC, which is subject to IND approval. 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 include our ability to raise the necessary capital to fund our operations and to find partners to supplement our capabilities and resources, our ability to submit and get approved our pending IND, as well as such other factors that 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 Biotech can be found at www.PharmaCyte.com. Information may also be obtained by contacting PharmaCyte's Investor Relations Department.

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