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FDA Formally Accepts PharmaCyte Biotech's Drug Master File 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 the Drug Master File (DMF) that its partner, Austrianova, filed with the U.S. Food and Drug Administration (FDA) has been accepted without any questions or suggested changes.

The FDA's Center for Biologics Evaluation and Research (CBER) successfully processed PharmaCyte's DMF, which provides all confidential and detailed information covering the production of the CypCaps™ final product that 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, "CBER's acceptance and processing of our Drug Master File without any questions or comments is a credit to the painstaking work and dedication by Austrianova and our consultants to ensuring that the entire process is properly conducted and completed before any further documents are submitted to the FDA.

"We now look forward to presenting the FDA with our Investigational New Drug Application very soon for our planned clinical trial in locally advanced, inoperable pancreatic cancer."

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. 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 things, 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 encapsulating 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, as well as beta islet cells, to treat diabetes. The encapsulation whatever cell line shows the most promise 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.

Safe Harbor

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement because of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements due to the impact of numerous risk factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

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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Dr. Gerald W. Crabtree
Investor Relations:
PharmaCyte Biotech, Inc.
Investor Relations Department

Telephone: 917.595.2856
Email: Info@PharmaCyte.com

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