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PharmaCyte Biotech Receives U.S. FDA Clinical Hold Letter

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 clinical hold letter from the U.S. Food and Drug Administration (FDA) with respect to its Investigational New Drug Application (IND). The company had previously announced on October 2, 2020 that it has received notification from the FDA that its IND had been placed on clinical hold.

In order to lift the clinical hold, the FDA has informed the company that it needs to conduct several additional preclinical studies. The FDA also requested additional information regarding several topics, including data, manufacturing information and product release specifications.

In addition, the FDA requested that several items not related to the clinical hold be addressed via submission of an IND amendment. Specifically, the FDA requested that the company perform qualification studies for the drug substance filling step to ensure that the product remains sterile and stable during the filling process. The FDA also requested additional information, discussion and clarification on several other topics.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, said, "Our team of experts is developing action plans to address the clinical hold letter. Since the FDA's letter included a lengthy list of items and several preclinical studies, at this time it's impossible to say when the company will be in a position to submit a complete response to the FDA. One big reason for the uncertainty is because some of the preclinical studies will be performed by outside third-party laboratories. Also, we are planning to request a meeting with the FDA about some of its requests. So, this is currently a very fluid situation."

Once PharmaCyte files its response to the clinical hold letter, the FDA will have 30 days to review the material submitted by PharmaCyte and make its decision whether to lift the hold.

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 is being 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 we believe 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 to treat diabetes. The encapsulation of the cell lines 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 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. 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 satisfactorily address the issues raised by the FDA in order to have the clinical hold on our IND removed, 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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