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# PharmaCyte Biotech Receives Medical Devices Registration and Submits Pre-EUA Application to the FDA for COVID-19 Diagnostic Kit

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 Medical Devices Establishment Registration with the FDA's Center for Devices and Radiological Health (CDRH). The CDRH requires this registration for companies that plan to import medical devices from overseas suppliers. The company also established itself as the sole U.S. agent for Hai Kang Life Corporation Limited (Hai Kang) for the importation of SARS-CoV-2 in vitro diagnostic test kits. The company plans to market its PCR-based diagnostic tests kits to Clinical Laboratory Improvement Amendments (CLIA) certified labs throughout the United States.

The company also announced that it is in dialogue with the U.S. Food and Drug Administration (FDA) through a Pre-Emergency Use Authorization (EUA) submission to the FDA. An EUA is a legal means for the FDA to expeditiously approve new drugs and new medical devices during a declared national emergency. For COVID-19 diagnostic test kits, the FDA recommends that manufacturers and suppliers file a Pre-EUA with the FDA in order to interactively work towards an eventual EUA submission and approval by the FDA. The FDA encourages companies to file an early draft so that the FDA examiner can offer feedback to avoid delays during the review of the final EUA application.

Kenneth L. Waggoner, the Chief Executive Officer of PharmaCyte Biotech, stated, "We have satisfied all of the regulatory requirements to get our COVID-19 diagnostic test kits into the country and are actively working with our partner, Hai Kang, through the FDA's preferred process of a Pre-EUA submission, dialoguing with our assigned examiner towards a final EUA submission to and approval by the FDA."

**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. In addition, PharmaCyte is developing and preparing to obtain approval from the U.S. FDA to commercialize a Covid-19 diagnostic kit to meet a critical unmet medical need for such kits during the current pandemic.

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 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 developing the use of genetically modified liver cells and stem cells, as well as beta islet cells, to treat diabetes. The encapsulation will be done using the Cell-in-a-Box® technology. Once the encapsulated cells are implanted in a diabetic patient, they will function as a “bio-artificial pancreas” for purposes of insulin production.

PharmaCyte’s diagnostic test kits, which were developed by and licensed from Hai Kang Life Corporation Limited (Hai Kang), for detecting the SARS-CoV-2 virus is the Enhanced Real-Time PCR (ERT-PCR) method. The technology is the same as the previous test for the SARS outbreak in 2003 that was published in the New England Journal of Medicine, but the primers and probes used in the current test is specific for the novel coronavirus. This means test results are positive only if the SARS-CoV-2 target sequences are present in the test sample.

**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 statements regarding the viability of the technology that is the subject to the Hai Kang License Agreement (Agreement) with PharmaCyte, our ability to gain the necessary approvals to market and commercialize Products under the Agreement, and the timing and commencement of such commercialization. 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, 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 can be found at www.PharmaCyte.com. Information may also be obtained by contacting PharmaCyte’s Investor Relations Department.

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