September 2, 2020

PharmaCyte Biotech Announces IND Submitted to U.S. FDA for Clinical Trial in Locally Advanced, Inoperable Pancreatic Cancer

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a clinical-stage 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 submitted an Investigational New Drug application (IND) to the U.S. Food and Drug Administration (FDA) for a planned Phase 2b clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, commented, "Submitting this IND is the most important milestone the Company has met thus far in the clinical development of our leading product candidate. That's our therapy to combat what is truly a global unmet medical need for those patients with LAPC whose tumors no longer respond to the first line treatments of either Abraxane® plus gemcitabine or FOLFIRINOX.

"Now that the IND has been submitted, we must wait a minimum of 30 calendar days before initiating our clinical trial. During this time, the FDA has an opportunity to review the IND to ensure that it's complete and that the planned clinical trial research patients will not be subject to unreasonable risk. It also gives the FDA time to ask for more information and clarification about the information submitted.

"Completing and submitting our IND is the culmination of many years of hard work and dedication to ensure that we've dotted every 'I' and crossed every 'T' by our partner, Austrianova, all of our committed consultants and our team at PharmaCyte, including our Chief Operating Officer, Dr. Gerald W. Crabtree, our Consulting Chief Medical Officer, Dr. José Iglesias, and the Chairman of our Medical and Scientific Advisory Board, Dr. Matthias Löhr."

PharmaCyte's Consulting Chief Medical Officer, Dr. José Iglesias, stated, "I am pleased that PharmaCyte has submitted its IND to the FDA. The entire PharmaCyte team can now begin work to prepare for the clinical trial. Combining a unique biologic that consists of encapsulated genetically altered human cells with a well-known cancer drug to treat LAPC, PharmaCyte has the possibility of changing the way LAPC is treated in the future. This novel treatment modality may also hold the potential for extending the life span of patients with LAPC."

The proposed multicenter, randomized, open-label Phase 2b clinical trial is intended to evaluate the efficacy and safety of CypCaps™ (genetically engineered human cells encapsulated using the Cell-in-a-Box® technology) in combination with low doses of the

chemotherapy prodrug, ifosfamide, as compared to chemoradiation therapy with capecitabine plus external beam radiation therapy ("EBRT") or stereotactic body radiation therapy ("SBRT") alone. The study population will consist of approximately 100 patients. Patients will be randomized in a 1:1 ratio to either treatment with the study therapy or a comparator. The randomization will be stratified by previous treatment (Abraxane® plus gemcitabine or FOLFIRINOX) and the control arm choice (capecitabine/EBRT or SBRT alone).

The primary objective will be determined by progression free survival ("PFS"). The secondary objectives for this study are to determine if CypCaps™ plus low-dose ifosfamide will: (i) increase overall survival ("OS"); (ii) increase objective response rate; (iii) increase the rate of conversion of the pancreatic tumor from inoperable to operable; (iv) decrease the pancreatic cancer tumor marker CA 19-9; and (v) improve a patient's quality of life. In addition, this clinical trial will assess the safety and tolerability of CypCaps™ plus low dose ifosfamide.

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 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 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 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 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20200902005335/en/

Dr. Gerald W. Crabtree
Investor Relations:
PharmaCyte Biotech, Inc.
Investor Relations Department
Telephone: 917.595.2856
Email: Info@PharmaCyte.com

Source: PharmaCyte Biotech, Inc.