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PharmaCyte Biotech Provides Update on Status of Activities to Lift Clinical Hold

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® , today announced the efforts being undertaken by the Company to have the U.S. Food and Drug Administration (FDA) clinical hold lifted. These efforts are necessary so that PharmaCyte may proceed with its planned clinical trial in locally advanced, inoperable, pancreatic cancer (LAPC).

The Company's Chief Executive Officer, Kenneth L. Waggoner, discussed the background of the clinical hold stating, "On September 1, 2020, the Company submitted an Investigational New Drug Application (IND) to the FDA for our planned Phase 2b clinical trial in LAPC. On October 1, 2020, the Company received notice from the FDA that it had placed our IND on clinical hold. And on October 30, 2020, the FDA sent a letter to us setting forth the reasons for the clinical hold and specific guidance on what we must do to have the clinical hold lifted."

For the purpose of addressing the clinical hold, the Company has assembled a team of regulatory and scientific experts to respond to the items requested by the FDA. That team has been actively working to complete the list of items requested by the FDA. Those items can be found on pages 28 and 29 of PharmaCyte's latest Form 10-Q for the period ending January 31, 2021.

Mr. Waggoner then explained, "The Company is in varying stages of addressing the studies and acquiring the information requested by the FDA to have the clinical hold lifted. Thus far:

1. The Company has successfully completed a 3, 6, 9, and 12-month product stability study on the Company's clinical trial product (CypCaps™), including container closure integrity testing for certain timepoints; the next time point in this ongoing study will be at 18 months of product stability.
2. The Company has designed and commenced various additional studies recommended by the FDA, including a stability study on the cells from the Master Cell Bank (MCB) used to make the CypCaps, which are already at the 3-year stability timepoint, and further sequence analysis of the DNA encoding of the Cyp2B1 gene in the encapsulated cells in the CypCaps. It has also collated existing information on the reproducibility and quality of the filling of the MCB cells into vials ready for CypCaps manufacturing as requested by the FDA.
3. The Company has designed and commenced biocompatibility studies such as (i) a Subchronic and Chronic Toxicity study; (ii) a Skin Sensitization study; (iii) an Acute Systematic Toxicity study; (iv) an Ames test [Genotoxicity Bacteria and Reverse Mutation tests]; (v) an Intracutaneous test; (vi) a Complement Activation test; (vii) a Hemolysis test; (viii) an In Vitro Cytotoxicity test; and (ix) an In Vivo Micronucleus assay. To enable these tests to be performed, the Company has already manufactured

and delivered an additional 400 syringes of empty capsules. Some of the data being generated will also be used to demonstrate comparability with the CypCaps successfully used—in two earlier German clinical trials for pancreatic cancer.

4. The Company has designed and commenced studies designed to show that CypCaps are not in any way adversely affected by the catheters used by interventional radiologists to deliver them, nor by the contract media used to visualize the blood vessels during implantation of the CypCaps. Further, the studies are designed to demonstrate how robust the CypCaps are during delivery and use as well as to document that the syringes used to deliver the CypCaps will allow delivery consistently, smoothly and safely.
5. Austrianova is providing additional detailed confidential information to the FDA on the manufacturing process, including information on the improvements made to the product since the last clinical trials with respect to reproducibility and safety, but that have not changed the overall physical characteristics of the CypCaps. The Company is supporting Austrianova in this work.
6. The Company is in the process of updating its documentation to include (i) more pre-clinical data as discussed above, (ii) some additional parameters for release of the CypCaps, (iii) specifically recommending the catheters and contrast used to deliver the CypCaps as well as (iv) extending its discussion on immunology.
7. Finally, the Company has designed an abbreviated study in pigs to address biocompatibility and long-term implantation of the capsules. This animal study will complement the positive data already available from the previous human clinical trials showing the safety of CypCaps implantation for up to two years in humans.
8. The Company feels that the carcinogenicity data obtained to date, together with the long-term data from the two previous German trials, show that CypCaps are unlikely to cause any long-term cancer. Furthermore, the patients who will be treated with CypCaps are already suffering with inoperable, late-stage pancreatic cancer, and chemotherapeutics, like ifosfamide, (the drug given at low concentrations with the CypCaps), are approved for treatment of cancer even through it is known to have a carcinogenic potential. Indeed, virtually all anti-cancer treatments used today by their very nature have an inherent potential to cause cancer. Moreover, the cells within the CypCaps are primed by ifosfamide to commit cell suicide if they try to divide."

Mr. Waggoner continued, "The list of items that we have been addressing is lengthy, time consuming and costly. Some of the studies required by the FDA caused us to find suitable partners and Contract Research Organizations to assist us in the work. But our team has been working tirelessly on every item and will continue to do so until we have done all that we can to satisfy the FDA requests. In addition, we plan to request a meeting with the FDA for further guidance and to update them on the progress that we have made.

"As we continue to reach milestones on the requested studies, we will strive to report on the material developments that we believe will allow us to get the clinical hold lifted."

To learn more about PharmaCyte's pancreatic cancer therapy and how it works inside the body to treat locally advanced inoperable pancreatic cancer, we encourage you to watch PharmaCyte's documentary video complete with medical animations at: https://www.PharmaCyte.com/Cancer.

About PharmaCyte Biotech

PharmaCyte Biotech, Inc. 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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