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PharmaCyte Discusses Phase 2b Clinical Trial in Pancreatic Cancer

LAGUNA HILLS, Calif.--(BUSINESS WIRE)-- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a clinical stage biotechnology company focused on developing targeted cellular therapies for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, today explains PharmaCyte's plans to conduct a Phase 2b clinical trial.

When PharmaCyte met with the FDA in January of 2017, PharmaCyte's pre-IND meeting submission was predicated on PharmaCyte conducting a Phase 2b trial. During discussions with the U.S. Food and Drug Administration (FDA), PharmaCyte asked whether the data from that planned trial could be considered "pivotal" and thus support registration for marketing purposes. The FDA indicated that this was a possibility, but that the trial would have to be much larger than PharmaCyte was planning and the data would have to be markedly superior to the data seen with the comparator treatment.

PharmaCyte's decision to conduct a Phase 2b trial rather than a pivotal trial was made relatively recently based on advice from PharmaCyte's consulting oncologists, Chief Medical Officer and information obtained from PharmaCyte's Advisory Board. PharmaCyte must rely on data from two European trials from 27 patients that were conducted about 20 years ago. The data from these trials are incomplete when compared to what is now required by the FDA to support a pivotal trial.

The Phase 2b trial is designed to determine how effective and safe multiple courses of ifosfamide will be in patients with locally advanced, non-metastatic, inoperable pancreatic cancer (LAPC) and how PharmaCyte's treatment compares to a commonly used treatment for LAPC after patients' tumors no longer respond following 4 to 6 months of the combination therapy of gemcitabine and Abraxane®. PharmaCyte is designing a Phase 2b clinical trial that, if successful, it believes will give the company a much more solid foundation for dealing with the FDA with the goal of bringing its pancreatic cancer therapy to market.

The planned Phase 2b trial will be significantly larger than the original Phase 2b trial PharmaCyte previously discussed with the FDA and will include multiple courses of low dose ifosfamide (the earlier trials used only two courses). This trial will also provide better statistical analyses of PharmaCyte's therapy for LAPC and the comparator arm in terms of survival and safety. Also, the possibility exists that if the data from PharmaCyte's therapy are significantly better than the data from the comparator arm, this may allow PharmaCyte to apply to the FDA for accelerated approval.

About PharmaCyte Biotech

PharmaCyte Biotech 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 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, store and release insulin in response to the levels of blood sugar in the human body. 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.

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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