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PharmaCyte Biotech Clears Major Milestone on Path to FDA Clinical Trial

NEW YORK, NY -- (Marketwired) -- 05/05/16 -- PharmaCyte Biotech (OTCQB: PMCB) has now reached a point in its life cycle where it is ready to start working with the U.S. FDA to get the company's Phase 2b clinical trial in advanced pancreatic cancer underway. Let that sink in for a moment. PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, has taken up the mantle to move the company's signature technology, Cell-in-a-Box®, to the clinic. And now, three short years later, he has the small biotech on the doorstep of what could be an eye-opening clinical trial to treat pancreatic cancer patients.

According to the American Cancer Society's cancer statistics for 2016, pancreatic cancer is the third leading cause of cancer-related deaths in the United States, and it's one of the few cancers for which survival has not improved substantially over nearly 40 years. But help could be on the way. After PharmaCyte announced last week that the live-cell encapsulation facility where its Cell-in-a-Box® capsules are produced is now current Good Manufacturing Practices or cGMP-compliant, the company cleared what was a major milestone on the way to a clinical trial and is now closer than ever to taking on the challenge of improving the lives of pancreatic cancer patients.

These are truly exciting times at PharmaCyte, and with the cell encapsulation facility now cGMP-compliant, the company can set its sights on first requesting a pre-IND (Investigational New Drug application) meeting with the FDA to discuss the design of its upcoming clinical trial.

This pre-IND meeting will be crucial to developing a relationship with the FDA and getting the necessary answers and guidance moving forward that will allow PharmaCyte to submit its formal IND to the FDA. The pre-IND meeting and the IND submission to the FDA are the next two major milestones for PharmaCyte and its investors.

With the encapsulation facility now ready for the production of clinical trial material, let's look at the trial design that PharmaCyte has announced for its Phase 2b clinical trial:

- PharmaCyte's pancreatic cancer therapy consists of placing microcapsules containing genetically engineered live cells near the blood supply to the pancreas. The cancer prodrug ifosfamide is then given at one-third the normal dose. When the blood carries the chemotherapy drug to where the capsules have been placed, activation of the drug takes place right at the source of the cancer instead of in the patient's liver, which eliminates any side effects in these patients.

- The trial will be a multi-site trial held in both the United States and Europe. It will also be an open-label trial in which the patients will be randomized between two study groups. The trial has been designed to meet a clear unmet medical need that exists for a particular group of pancreatic cancer patients.

- The randomization ratio of patients between the two study groups will be 1:1 (an equal number of patients will be randomly assigned to the capecitabine + radiation group and the PharmaCyte pancreatic cancer therapy group).

- Only patients who have locally advanced, non-metastatic, inoperable cancer and whose tumors no longer respond after 4-6 months of treatment with either the widely used Abraxane® + gemcitabine combination therapy or FOLFIRINOX, will be eligible for the trial. These patients are usually treated with the combination of the chemotherapy drug capecitabine + radiation, but this treatment is only marginally effective and is quite toxic for the patients.

- Study sites under consideration in the U.S. include the Mayo Clinic in Scottsdale, Arizona, the Beth Israel Deaconess Cancer Center in Boston, the Dana-Farber Cancer Institute also in Boston, the Baylor Cancer Center in Dallas, Texas, Cedars-Sinai Medical Center in Los Angeles, as well as sites in Germany and Spain.

- It is believed that 84 patients will be required to complete the study, although fewer may be required based upon the data developed during the trial.

- Unlike in earlier clinical trials using PharmaCyte's pancreatic cancer therapy where patients received only two cycles of therapy with ifosfamide, multiple cycles of ifosfamide will be given to those being treated with PharmaCyte's pancreatic cancer therapy. This will continue until the patients' tumors no longer respond to PharmaCyte's therapy or until treatment-related toxicity accumulates to unacceptable levels.

And the best news of all for investors heading into these exciting times is that PharmaCyte has been awarded the Orphan Drug designation by both the U.S. FDA and the European Medicines Agency (EMA). This designation means that the company's pancreatic cancer therapy will have complete protection and market exclusivity for years to come. After PharmaCyte's therapy is approved for marketing by these two regulatory agencies, they will enjoy 7 years of market exclusivity in the United States and 10 years of protection in the European Union.

PharmaCyte's CEO also recently stated that the company's pancreatic cancer therapy qualifies for 12 years of data exclusivity because it is considered a "biologic" as outlined by the Biologics Price Competition and Innovation Act (BPCIA).

So, as the company marches headlong into a Phase 2b clinical trial in the U.S. and Europe with a built in "hard stop" about half way through the trial to review the data, there is no better time than the present to get excited about this small biotechnology company and what could very well be a significant contribution to the treatment of pancreatic cancer.

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