March 31, 2016

PharmaCyte Biotech Finalizes Design of Pancreatic Cancer Clinical Trial and Identifies Trial Sites under Consideration

SILVER SPRING, Md., March 31, 2016 (GLOBE NEWSWIRE) -- PharmaCyte Biotech, Inc. (OTCQB: PMCB), a clinical stage biotechnology company focused on developing targeted therapies for cancer and diabetes using its live-cell encapsulation technology, Cell-in-a-Box®, today announced the final design of its clinical trial for patients with advanced pancreatic cancer. The clinical trial design was developed with Translational Drug Development (TD2), America's premier oncology Contract Research Organization, as well as with renowned pancreatic cancer specialists consulting with PharmaCyte.

PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, stated, "The trial is designed to determine if PharmaCyte's pancreatic cancer treatment (the combination of micro-capsules that contain genetically modified human cells which convert the cancer prodrug ifosfamide into its "cancer-killing" form at one-third the normal dose) can satisfy a clear unmet medical need that exists for patients with locally advanced, inoperable pancreatic cancer who no longer respond to the current standard of care. Most of these patients are initially treated with the combination of nab-paclitaxel (Abraxane®) plus gemcitabine or the four-drug combination known as FOLFIRINOX. When these patients' tumors no longer respond to treatment with these regimens, the next standard of care offers little to no benefit. It is then that these patients are often treated with the combination of the anticancer drug capecitabine plus radiation therapy. However, this combination is only marginally effective in stopping the progression of the disease. In PharmaCyte's clinical trial, our pancreatic cancer therapy will be compared "head to head" with the capecitabine/radiation combination to demonstrate that it is clearly superior in treating these patients while maintaining a superior quality of life during the therapy."

Major factors in the overall trial design are:

- The clinical trial will be international (United States, Europe and possibly Australia), multi-site, open-label and randomized.

- Study sites under consideration in the United States include the Mayo Clinic in Scottsdale, Arizona, the Beth Israel Deaconess Cancer Center and the Dana-Farber Cancer Institute both in Boston, Massachusetts, the Baylor Cancer Center in Dallas, Texas, the City of Hope Cancer Center in Los Angeles, California, and sites in Germany and Spain.

- 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).

- As many as 84 patients will be required to complete the study, although fewer may be required based upon the data developed during the trial.

- Only patients who have locally advanced, non-metastatic, inoperable cancers and whose tumors no longer respond after 4-6 months of treatment with either the nab-paclitaxel (Abraxane®) + gemcitabine or FOLFIRINOX regimens will be eligible for the study.

- Unlike the earlier clinical trials using PharmaCyte's pancreatic cancer therapy where patients received only two doses of 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.

Mr. Waggoner concluded, "We feel that the major factors that needed to be considered for the development of a complete clinical trial protocol have now been addressed. Of course, as we continue to move toward our clinical trial, slight changes that benefit the overall trial design could certainly be addressed and lead to further refinement of the trial. Special appreciation for reaching this point must be given to the renowned pancreatic cancer experts who have played such a major role in the trial design. With these developments, we are yet another step closer to the commencement of our clinical trial which we believe will satisfy the clear unmet medical need experienced by patients with locally advanced, but inoperable, pancreatic cancer who no longer respond to the gold standard of care."

About PharmaCyte Biotech
PharmaCyte Biotech is a clinical stage biotechnology company focused on developing and preparing to commercialize treatments for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as "Cell-in-a-Box®." This unique and patented technology will be used as a platform upon which treatments for several types of cancer and diabetes are being developed. PharmaCyte's treatment for cancer involves encapsulating genetically modified live cells that convert an inactive chemotherapy drug into its active or "cancer-killing" form. These encapsulated live cells are placed as close to a cancerous tumor as possible. Once implanted in a patient, a chemotherapy drug which needs to be activated in the body (ifosfamide) is then given intravenously at one-third the normal dose. The ifosfamide is carried by the circulatory system to where the encapsulated cells have been placed. When the ifosfamide, which is normally activated in the liver, comes in contact with the encapsulated live cells, activation of the chemotherapy drug takes place at the source of the cancer without any side effects from the chemotherapy. This "targeted chemotherapy" has proven remarkably effective and safe to use in past clinical trials.

In addition to developing a novel treatment for cancer, PharmaCyte is developing a treatment for Type 1 diabetes and Type 2 insulin-dependent diabetes. PharmaCyte plans to encapsulate 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.

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This press release may contain forward-looking statements regarding PharmaCyte and its future events and results that involve inherent risks and uncertainties. The words

"anticipate," "believe," "estimate," "expect," "intend," "plan" and similar expressions, as they relate to PharmaCyte or its management, are intended to identify forward-looking statements. Important factors, many of which are beyond the control of PharmaCyte, could cause actual results to differ materially from those set forth in the forward-looking statements. They include PharmaCyte's ability to continue as a going concern, delays or unsuccessful results in preclinical and clinical trials, flaws or defects regarding its product candidates, changes in relevant legislation or regulatory requirements, uncertainty of protection of PharmaCyte's intellectual property and PharmaCyte's continued ability to raise capital. PharmaCyte does not assume any obligation to update any of these forward-looking statements.

More information about PharmaCyte Biotech can be found atwww.PharmaCyte.com. It can also be obtained by contacting Investor Relations.

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Source: PharmaCyte Biotech, Inc.