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PHARMACYTE BIOTECH

PharmaCyte Biotech Issues Update on Preparations for Its Pancreatic Cancer Clinical Trial

SILVER SPRING, Md., Feb. 22, 2016 (GLOBE NEWSWIRE) -- PharmaCyte Biotech, Inc. (OTCQB:PMCB), a clinical stage biotechnology company focused on developing targeted treatments for cancer and diabetes using its signature live-cell encapsulation technology, Cell-in-a-Box®, issued an update on its efforts to get PharmaCyte's pancreatic cancer treatment into a Phase 2b clinical trial. In the update PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, explains why the expected 'start date' for PharmaCyte's clinical trial in pancreatic cancer remains difficult to announce with certainty and addresses a number of issues that PharmaCyte's shareholders have raised related to the upcoming clinical trial.

"First and foremost, there is the issue of the redesign of the clinical trial in pancreatic cancer. As our longtime investors are aware, the clinical trial was originally designed to compare our pancreatic cancer treatment 'head to head' with the combination of Abraxane® + gemcitabine in patients with advanced, inoperable pancreatic cancer. When the Abraxane® + gemcitabine combination was approved by the FDA (after an 861 patient trial that took Celgene several years to complete) and later became the 'gold standard' of care for advanced pancreatic cancer worldwide, it became obvious that the original trial design was no longer feasible. Getting patients to enroll in the trial would have been very problematic. Understandably, we felt patients with pancreatic cancer would opt for the new 'gold standard' of care rather than enrolling in a clinical trial to prove that PharmaCyte's treatment is superior to the gold standard. In addition, to prove success the originally designed trial would have involved hundreds of patients, taken years to complete and would have been so expensive to conduct that only "big pharma" could have afforded to carry it out successfully.

"With invaluable input from three of the world's leading authorities in pancreatic cancer, the trial was completely redesigned to what it is today. We continue to improve the design with the hope that it will result in the best possible outcome for pancreatic cancer patients and that PharmaCyte's treatment will become a recognized treatment for a significant segment of those with pancreatic cancer. In the newly designed trial, PharmaCyte's pancreatic cancer treatment will be compared against the best available therapy (the combination of chemotherapy drug capecitabine + radiation) in patients whose pancreatic cancer no longer responds to either the Abraxane® + gemcitabine combination or a 4-drug combination known as FOLFIRINOX. Adding FOLFIRINOX to the inclusion criteria is a new element and expands the potential patient population that will be available to participate in the trial. These therapies are by far the most widely used around the world to treat advanced, inoperable pancreatic cancer. Patients in our trial will have tumors that are locally advanced (they have not spread to different organs in the body), but nevertheless are inoperable. Instead of conducting the trial in just Australia, as was proposed in the original trial design, we plan to conduct the trial in the United States with study sites in Europe and Australia.

“In addition to the direct effects of the comparator treatment on the growth of a patient’s cancerous tumor, measurements will be taken to determine if our treatment can convert an inoperable tumor to an operable one, which the capecitabine + radiation combination cannot do well, if at all. If our treatment is successful in doing so, imagine what that would mean to the numerous patients around the world who suffer from this dreadful and deadly disease and to their prospects for a significantly increased lifespan. The new trial design also eliminates the need for a separate clinical trial on the effects of our pancreatic cancer treatment on the unbearable and untreatable pain that is associated with pancreatic cancer in 20-25% of patients. In the new trial design, measurements that will ‘track’ a patient’s pain and a patient’s need for pain medication have been incorporated into the trial.

“Needless to say, the redesign of the entire clinical trial was labor intensive and took many months to complete. All three of our world-renowned pancreatic cancer experts agree enthusiastically with the new trial design and believe that it provides PharmaCyte with the opportunity to satisfy a clear unmet medical need by providing a large number of pancreatic cancer patients with a successful treatment option that does not exist today. They also believe that the trial can be conducted with far fewer patients, take less time and cost a great deal less money to complete than the trial that was originally designed might have cost PharmaCyte.”

Waggoner continued, “Second, there is the issue of ensuring that the manufacturing facility that Austrianova has built in Bangkok, Thailand, which encapsulate the live cells that convert the cancer prodrug ifosfamide into its cancer-killing form, meets current Good Manufacturing Practices (cGMP) standards. This is an absolute requirement for drug regulatory authorities around the world before a clinical trial can begin. All aspects of the construction of the facility need to be qualified, validated and documented, as does every item used within the facility. Numerous ‘standard operating procedures’ must also be written, inspected for quality and clarity and retained for future use. Test ‘runs’ of the encapsulation process must also be qualified and validated. Even the employees who work in the facility must meet stringent regulations. Literally ‘volumes’ of documentation result from these activities. This work is extremely labor intensive and time-consuming, but is currently being accomplished by our colleagues at Austrianova.

“The process to assure that Austrianova’s live-cell encapsulation facility meets cGMP standards is well underway. After Chamow & Associates (Chamow) inspected the facility in December 2015, they prepared a detailed audit report for Austrianova to use as a blueprint to complete the work necessary to insure that the facility is cGMP compliant. Twice monthly PharmaCyte, Translational Drug Development (TD2), Chamow and Austrianova hold a lengthy teleconference to discuss the progress that is being made in completing the items necessary for the facility to become cGMP compliant and in generating the bulk of the CMC information needed for the Investigational New Drug application (IND) we plan to submit to the FDA. A detailed Gantt chart has been prepared to monitor the progress being made and to assist in keeping the project on schedule.

“Evidence of the cGMP compliance of the encapsulation facility must be presented to drug regulatory authorities as part of the Chemistry, Manufacturing and Controls (CMC) section of the IND. It must be deemed satisfactory by the FDA before the clinical trial can begin. The cGMP facility information makes up the bulk of the CMC information package, which, in turn, makes up the largest and arguably the most important part of the IND. PharmaCyte is very

fortunate to have retained Chamow, an outstanding biopharmaceutical consulting firm, that specializes in the inspection of facilities for cGMP compliance and in the preparation of the CMC section of INDs. Chamow is working in concert with TD2 to prepare the CMC section of our IND for the facility in Thailand."

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.

Safe Harbor

This press release may contain forward-looking statements regarding PharmaCyte Biotech 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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