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PharmaCyte Biotech Discusses Patient Enrollment and TD2's Role in Upcoming Clinical Trial

LAGUNA HILLS, Calif., Feb. 21, 2017 (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®, released today the third article in a series of Q&A articles that will be conducted with some of the key team members of PharmaCyte's upcoming clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

This interview-style Q&A article is with Dr. Stephen Gately, the President and Chief Executive Officer of Translational Drug Development (TD2), a world-class drug development service specializing in getting the newest and best oncology treatments to cancer patients as quickly as possible, and PharmaCyte's CRO for its upcoming clinical trial in LAPC.

As the CRO for PharmaCyte's upcoming clinical trial in pancreatic cancer, can you explain what the role of TD2 has been before the trial begins and what that role will be once the trial begins?

Dr. Stephen Gately: "As the CRO for PharmaCyte, TD2 has been instrumental in the development of the study design and developing the plans to operationalize the study. TD2 will assign a project manager, and this individual is going to be the single point of contact for the project. Study sites and investigators will be recruited and qualified using feasibility questionnaires and on-site visits during the time prior to the start of the trial.

"TD2 will continue to work with PharmaCyte's imaging group to develop the procedure manual for implanting the CypCaps. This will require written procedures and instructions as well as developing a training and qualifying program for the site interventional radiologist. The goal is to have this completed prior to study start so that patient enrollment won't be delayed.

"TD2 will continue to build the clinical database where the clinical date will be entered and stored. The goal is to have the database ready to go live prior to study start.

"There are a number of plans that are written to detail the activities for data management, medical monitoring, safety management, laboratory manual, pharmacy manual, site monitoring and the statistical analysis plan."

Once PharmaCyte has the go-ahead to begin its clinical trial, what is the patient enrollment process?

Dr. Stephen Gately: "Once given the go-ahead (IND has cleared the FDA), the project manager will begin focusing on getting the sites up and running. Contracts and budgets need

to be put in place with each site. The protocol will need to be reviewed and approved by each site's Institutional Review Board. A series of documents, called essential documents, need to be collected from the sites and need to be on file at TD2. Once this has been completed then a site activation visit will take place for each site. The purpose of this visit is to educate and train the site how to conduct the study appropriately. The training and qualification of the interventional radiologist must be completed by this time as well. Once this has been completed, the site will be activated and CypCaps will be shipped to the site.

"Once the site has received the CypCaps then the screening process can begin. The principal investigator or sub-investigator will identify a patient, and the patient will be screened in accordance with the procedures listed in the protocol. The patient must meet the inclusion and exclusion criteria under the protocol to be eligible for the study. The patient's records will be reviewed by the medical monitor, and the patient will be declared eligible. The site will schedule the patient for the procedure. The site personnel will enter the patient into the clinical database and begin data collection."

How does TD2 find patients?

Dr. Stephen Gately: "TD2 will work with qualified sites that have an interest in treating patients with pancreas cancer. These sites have been successful in accruing patients to pancreas cancer clinical trials. The site will screen their patients as described above."

We understand that there are databases of potential patients that TD2 has access to fill PharmaCyte's trial and others. How do these patients end up in the databases?

Dr. Stephen Gately: "With the Federal Electronic Medical Records (EMR)) mandate, all health care facilities are required to convert all medical records to electronic medical records (EMR). An electronic health record (EHR), or electronic medical record (EMR), refers to the systematized collection of patient and population electronically stored health information in a digital format. These records can be shared across different health care settings. Records are shared through network-connected, enterprise-wide information systems or other information networks and exchanges. EHRs may include a range of data, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, vital signs, personal statistics like age and weight and billing information.

"There are a number of technologies that have been developed that can search these records using the eligibility criteria from the study to identify patients."

Approximately how many clinical trial sites in the U.S. does TD2 anticipate will be part of PharmaCyte's trial? Can you identify some of the candidates?

Dr. Stephen Gately: "TD2 is planning on opening 12-15 sites for this study. This number may change during the course of the study. The sites will be located throughout the United States. These sites have been selected because they have been successful in accruing patients to pancreas cancer studies and have the expertise required to do the procedure to implant the CypCaps. For instance, Dr. Manuel Hidalgo as the principal investigator of the clinical trial will be enrolling patients at the Beth Israel Deaconess Medical Center in Boston. Candidates for the trial include Hoag Hospital Newport Beach, Cedars-Sinai Medical Center in Los Angeles, Baylor University Medical Center Dallas and HonorHealth Scottsdale Shea

Medical Center.”

During the clinical trial how closely will TD2 work with the Principal Investigator, Dr. Manuel Hidalgo?

Dr. Stephen Gately: “Communication is the key to success of any project. The TD2 project manager will have biweekly calls scheduled with Dr. Hidalgo, PharmaCyte and site investigators to discuss the progress of the trial. These discussions will include, but will not be limited to, patient care, safety issues, data collection, enrollment rates and any other concerns that come up.”

TD2 has been involved in many clinical trials. What are your early impressions of PharmaCyte's pancreatic cancer therapy?

Dr. Stephen Gately: “New and effective therapies for patients with pancreas cancer are clearly needed. We have reviewed PharmaCyte’s prior human clinical data and are encouraged that this approach may provide clinical benefit for patients with pancreas cancer. TD2 is grateful for the opportunity to work with PharmaCyte’s team on this exciting project.”

About PharmaCyte Biotech

PharmaCyte Biotech is a clinical stage biotechnology company developing 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. These encapsulated cells are implanted as close to the patient’s cancerous tumor as possible. 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 comes in contact with the encapsulated cells they act as an artificial liver and activate the chemotherapy drug at the source of the cancer. This “targeted chemotherapy” has proven effective and safe to use in past clinical trials and results in no side effects.

In addition to developing a novel therapy for cancer, PharmaCyte is developing a treatment for Type 1 diabetes and insulin-dependent Type 2 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. Once the encapsulated cells are implanted in a diabetic patient they will function as a “bio-artificial pancreas” for purposes of insulin production.

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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 as a result of the impact of a number of 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 atwww.PharmaCyte.com. It can also be obtained by contacting Investor Relations.

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