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PharmaCyte Biotech Discusses Upcoming Clinical Trial with Principal Investigator Dr. Manuel Hidalgo

LAGUNA HILLS, Calif., Jan. 10, 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 second article in a series of Q&A articles that will be conducted with some of the key team members of PharmaCyte's planned clinical trial in locally advanced, inoperable pancreatic cancer (LAPC).

This article, which comes one week before PharmaCyte's pre-IND meeting with the FDA, is with Dr. Manuel Hidalgo, the Principal Investigator of PharmaCyte's clinical trial in LAPC. Dr. Hidalgo is Chief of the Division of Hematology/Oncology and the Director of the Rosenberg Clinical Cancer Center of the Beth Israel Deaconess Medical Center in Boston, Massachusetts. He is also a Member of the Faculty of Medicine of the Harvard Medical School and Co-Director of the international Pancreatic Cancer Research Program.

What are your thoughts on PharmaCyte's therapy for LAPC and its technology Cell in a Box®?

Dr. Manuel Hidalgo: "Locally advanced inoperable pancreas adenocarcinoma (pancreatic cancer or PDAC) is a significant health issue. About 30% of patients with pancreatic cancer present with disease that is localized but cannot be resected in full. These patients are now managed with chemotherapy and radiation therapy with poor results. One of the reasons why these results are poor is because the concentration of chemotherapy that reaches the pancreas tumor may be too low to exert its therapeutic effects. However, Cell in a Box® is a new innovative technology that may result in higher concentrations of chemotherapy at the site of the pancreas cancer. The way this is achieved is by encapsulating living cells that have the capacity to enzymatically activate a drug called ifosfamide in the pancreas tumor itself. By doing so, the concentration of active drug in the tumor bed increases which likely results in better efficacy while there is less systemic exposure to the active drug with the corresponding decrease in toxicity."

What did you see in the early data from the 2 previous clinical trials that gives you confidence with PharmaCyte's therapy heading into the upcoming clinical trial?

Dr. Manuel Hidalgo: "The data is promising and suggests this approach should be further tested. In addition to early evidence of efficacy, the study showed minimal toxicity, consistent with decreased systemic exposure to the active drug and improvement in quality of life. These are very important observations. However, the previous studies were small, and we need additional data."

As the Principle Investigator for the upcoming clinical trial, why is it important for you to be involved with this clinical trial?

Dr. Manuel Hidalgo: “As investigators involved in PDAC research, we are always looking for new, safe strategies to improve patient outcome. In this disease, we really need innovation. We need new approaches and strategies, and Cell in a Box® is indeed a new strategy. I am very excited because of the novelty of the approach. I am also very glad to be working with a terrific group of people both on the PharmaCyte side and in the investigators team.”

You have been a part of so many clinical trials. What have you learned or experienced from those previous clinical trials that you can bring to this clinical trial?

Dr. Manuel Hidalgo: “When conducting a clinical trial, the most important thing is to preserve the safety of the subjects and integrity of the data. To that end, it is critical to meticulously select the subjects and follow the protocol. As overall Principal Investigator, I will be working closely with other investigators and the sponsor to make sure the study is conducted according to good clinical practice and other pertinent regulations. Of course, in the day to day, there are always special situations. Here is where the expertise of the investigators team plays an important role. The two key features are to properly document every observation and to communicate and ask any question that may emerge.”

As a long-time friend and colleague of Dr. Von Hoff and relatively new friend and colleague of Dr. Löhr, what are your thoughts about being teamed up with them for this upcoming clinical trial?

Dr. Manuel Hidalgo: “I am naturally very excited with the opportunity to work with such terrific doctors and investigators. The conduct of the study is a team effort, and having such high caliber investigators on the team provides us with the expertise needed for the success of this clinical trial.”

What experiences can you draw on from the Abraxane® clinical trial that you were involved in with Dr. Von Hoff that you can bring to PharmaCyte’s clinical trial?

Dr. Manuel Hidalgo: “Through a series of clinical and preclinical studies led by Dr. Von Hoff, myself and many other excellent investigators, we showed that Abraxane® is effective in pancreatic cancer leading to its approval. The development of this drug provided us with a firsthand experience on how to take a new agent from concept to approval. We will now apply all of this knowledge and expertise to develop Cell in a Box® for pancreas cancer treatment. These are obviously very different technologies, but the principles of conducting a high quality step-wise development plan are similar.”

For those who aren't familiar with the clinical trial process and the development of a therapy for pancreatic cancer, why is it important to have an experienced team surrounding PharmaCyte's technology heading into its clinical trial?

Dr. Manuel Hidalgo: “I cannot emphasize enough how important having an experienced team is to conducting any clinical trial, but even more a trial with a new technology like Cell in a Box®. Elements of an experienced team range from proper patient selection to the delivery of the treatment and monitoring safety and efficacy. Each one of these elements,

just to name a few, requires careful attention to details, proper documentation and communication. As this is a new technology and is a non-conventional one, these details become even more important. This is like a performance. The sheet music (protocol) is important but the conductor (investigator) and the orchestra (research team) are also critical."

What do you think about going head to head with gemcitabine as the comparator arm in PharmaCyte's clinical trial?

Dr. Manuel Hidalgo: "While patients with locally advanced pancreatic cancer are managed in many different ways around the globe, one can argue that the data from the LAP007 trial shows that gemcitabine alone is as good as gemcitabine combined with radiation therapy. Based on these data, from a regulatory perspective, we think gemcitabine alone is the accepted standard of care and have written the protocol that way."

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

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