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PharmaCyte Biotech Discusses Upcoming Clinical Trial in Pancreatic Cancer with First Principal Investigator

LAGUNA HILLS, Calif., Dec. 07, 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®, released today the first 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). PharmaCyte's first Q&A article is with Dr. Matthias Löhr of the famed Karolinska Institute in Stockholm, Sweden. Dr. Löhr was the Principal Investigator of the two earlier clinical trials using the Cell-in-a-Box® technology in patients with advanced, inoperable pancreatic cancer.

As PharmaCyte prepares to meet with the FDA in a Pre-IND meeting, what are your general thoughts of the Cell-in-a-Box® plus low dose ifosfamide therapy for pancreatic cancer once again getting a chance to prove itself in patients?

Dr. Matthias Löhr: "I feel very confident and also happy to see the revival of this treatment concept. I consider Cell-in-a-Box® as a platform technology. The previously raised concerns relating to the consistent reproducibility of the micro-capsules have been met by Austrianova in the meantime. Pancreatic cancer is a medical emergency (https://www.researchgate.net/publication/265394214_Pancreatic_cancer_should_be_treated_ and is rising amongst the cancer related deaths, this year surpassing breast cancer to become number three, and by 2030 to become number two."

As the Principle Investigator of both of the earlier clinical trials, what are some of the highlights you recognized that you feel will once again be seen in PharmaCyte's upcoming trial?

Dr. Matthias Löhr: "When we treated the first patients, they did not believe that they were receiving chemotherapy because there were NO side effects at all in the initial trial. That should be the case in PharmaCyte's upcoming trial. Besides this very subjective impression, albeit repeated by all patients, we measured the quality of life, which was excellent - considering the dire disease. We will be measuring the quality of life in the upcoming trial as well. Further, we saw an effect not only on the primary tumor in the pancreas (where the capsules were injected) but also in some patients on the liver metastasis. This can only be explained by an immunological bystander effect that will likely be investigated in more depth in the upcoming clinical trial. Finally, in the first trial, certain patients' tumors went from inoperable to operable. That is certainly a possibility in PharmaCyte's trial, especially since we will be giving more than two courses of ifosfamide like we did in the first trial."

Why do you feel this new trial design can succeed?

Dr. Matthias Löhr: “The locally advanced pancreatic cancers are not sufficiently covered by guidelines - there is no standard of care, hence a highly unmet medical need. This refers particularly to those patients who received first line therapy, e.g. a very strong one (FOLFIRINOX) or combination of gemcitabine with Abraxane®. AFTER this therapy, there is nothing left, especially an alternative with a low likelihood of side effects. The selection of these patients (group) is certainly to an advantage of the Cell-in-a-Box® technology, which is mostly localized, may have a systemic (immunological) effect and has virtually no side effects. We consider this an ideal setting to the advantage of our patients in this upcoming clinical trial.”

What are your thoughts on the benefits of using more rounds of the chemotherapy prodrug ifosfamide as PharmaCyte’s trial design calls for in this upcoming clinical trial?

Dr. Matthias Löhr: “This will definitively improve the outcome of the patients in this upcoming clinical trial. We couldn’t do this in the original trial(s) as we had no information on the stability of the capsules and activity of the cells converting the chemotherapy drug ifosfamide. This has changed now with the data developed from the first two trials. We will continue to administer ifosfamide until the patients receive no further benefit from our therapy. We can do that because we know the capsules are robust for at least two years and that the cells within them continue to convert ifosfamide during the life of the patient.”

What are your thoughts on going head to head with gemcitabine?

Dr. Matthias Löhr: “No sweat. Gemcitabine is still the standard, due to the excellent tolerability of the drug and will be the drug used second line, especially after heavy protocols such as FOLFIRINOX or gemcitabine/ Abraxane®. In this pretreated patient group, one has to use something with a very low profile on side effects. This is certainly the case with our Cell-in-A-Box®.”

What are your impressions of the team that surrounds the technology as PharmaCyte heads into its planned clinical trial?

Dr. Matthias Löhr: “PharmaCyte has the visionary capacity to see the potential of this platform technology, with pancreatic cancer being the first indication. They reached out to the original team, both those developing the technology and conducting the early phase clinical trials. Taking this knowledge on board is certainly the most important factor to ensure success. Further, with both Dr. Manuel Hidalgo and Dr. Daniel Von Hoff, two eminent oncologists with a lifetime track record in oncology and especially pancreatic cancer, the starting conditions could not be better.”

About PharmaCyte Biotech

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

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