

PharmaCyte Biotech's Encapsulation Technology Could Address Unmet Medical Need

SILVER SPRING, Md., Sept. 28, 2015 (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, released today the second in a series of articles that will serve to educate the public on its technology and how it is used in the treatment of advanced pancreatic cancer. This latest article, written by Dr. Matthias Löhr of the famed Karolinska Institute in Stockholm, Sweden, and the Chairman of PharmaCyte Biotech's Scientific Advisory Board, discusses the unmet clinical need of a large group of patients suffering from locally advanced pancreatic cancer.

PharmaCyte Biotech's Chief Executive Officer, Kenneth L. Waggoner, commented on Dr. Löhr's article, "Dr. Löhr understands the severity of the unmet medical need he addresses in his article as much as anyone. Dr. Löhr explains his rationale for believing there is an urgent need to develop a therapy for patients with pancreatic cancer that is not currently being addressed by the medical community. Our other prominent oncologists also believe that new therapeutic options are needed for those with locally advanced pancreatic cancer. We agree with Dr. Löhr that PharmaCyte Biotech's pancreatic cancer treatment has the potential to address squarely this unmet medical need."

The Unmet Clinical Need in Locally Advanced Pancreatic Cancer

Pancreatic cancer is a medical emergency⁽¹⁾. There is a highly unmet medical need for all patients as survival rates from pancreatic cancer are the lowest of all solid tumors. If nothing happens to change that situation, pancreatic cancer will become the number two cause of cancer-related deaths by 2030⁽²⁾. There is evidence for the use of chemotherapy to prevent possible relapse in patients whose pancreatic cancer tumors have been removed surgically, but this situation occurs in only 20% of all patients at best.

The large remaining group of patients whose tumors are inoperable may receive palliative chemotherapy (treatment designed to prolong survival and ease symptoms), but these patients only exhibit survival rates oscillating around 6 months. Recent progress in the chemotherapy of pancreatic cancer has pushed this survival to 10-11 months through the use of either the combination of gemcitabine and nab-paclitaxel (Abraxane $^{(8)}$)(3) or a rather harsh combination of conventional cancer chemotherapy drugs, known as FOLFIRINOX, that not all patients can tolerate⁽⁴⁾.

These therapeutic strategies are part of recent guidelines for the treatment of pancreatic cancer. In addition, evidence for "second-line" therapy for patients whose tumors continue to grow exists⁽⁵⁾. There is, however, a group of patients for whom we have nothing to offer today: patients with locally advanced disease (LAD) whose tumors are inoperable due to

overgrowth of the arterial blood vessels, namely the superior mesenteric artery (SMA) or the celiac trunk. Current practice is to treat these patients with what is termed "neoadjuvant" chemotherapy using gemcitabine plus nab-paclitaxel (Abraxane®) or FOLFIRINOX to reduce the size of their tumors to the point where they become operable. This strategy works in only about 20% of patients with LAD.

In about 30% of patients, while they are receiving neoadjuvant chemotherapy, their tumors advance and metastasize (spread to other organs). This makes their primary pancreatic cancer tumors no longer eligible for curative surgery, and therapy is usually continued as a palliative measure. However, for the group (about 50%) of patients whose tumors neither progress nor show signs of tumor reduction, i.e. patients who exhibit stable disease, there is no effective treatment alternative. For this cadre of patients, a localized tumor therapy, such as that being developed by PharmaCyte Biotech, could present a welcomed therapeutic option.

PharmaCyte Biotech's combination of encapsulated, live genetically-engineered cells capable of converting the cancer drug ifosfamide into its cancer-killing form implanted at the site of the tumor, followed by low doses of intravenously administered ifosfamide (6), may fill the unmet medical need that has escaped the medical community for far too many years. Results derived from the pending Phase 2b clinical trial could provide critical data to confirm this.

References:

- 1. Löhr JM. Personal view: Pancreatic cancer should be treated as a medical emergency. British Medical Journal, 2014; Vol. 349:g52612.
- 2. Rahib L, Smith BD, Aizenberg R, et al. Projecting cancer incidence and deaths to 2030: the unexpected burden of thyroid, liver, and pancreas cancers in the United States. Cancer Research, 2014; Vol. 74:2913-2921.
- 3. Von Hoff DD, Ervin T, Arena FP, et al. Increased survival in pancreatic cancer with nab-paclitaxel plus gemcitabine. New England Journal of Medicine, 2013; Vol. 369:1691-1703.
- 4. Conroy T, Desseigne F, Ychou M, et al. FOLFIRINOX versus gemcitabine for metastatic pancreatic cancer. New England Journal of Medicine, 2011; Vol. 364:1817-1825.
- 5. Pelzer U, Schwaner I, Stieler J, et al. Best supportive care (BSC) versus oxaliplatin, folinic acid and 5-fluorouracil (OFF) plus BSC in patients for second-line advanced pancreatic cancer: a phase III-study from the German CONKO-study group. European Journal of Cancer, 2011; Vol. 47:1676-1681.
- 6. Löhr M, Hoffmeyer A, Kroger J, et al. Microencapsulated cell-mediated treatment of inoperable pancreatic carcinoma. Lancet, 2001; Vol. 357:1591-1592.

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 Biotech's treatment for cancer involves encapsulating genetically modified live cells capable of converting an inactive chemotherapy drug (ifosfamide) 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, 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 ifosfamide, which is normally activated in the liver, comes in contact with the encapsulated live cells, activation of the 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 Biotech is developing a treatment for Type 1 diabetes and Type 2 insulin-dependent diabetes. PharmaCyte Biotech plans to encapsulate a human cell line which has been genetically engineered to produce, store and secrete insulin at levels in proportion 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 Biotech or its management, are intended to identify forward-looking statements. Important factors, many of which are beyond the control of PharmaCyte Biotech, 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 Biotech's intellectual property and PharmaCyte Biotech's continued ability to raise capital. PharmaCyte Biotech does not assume any obligation to update any of these forward-looking statements.

More information about PharmaCyte Biotech can be found at<u>www.PharmaCyte.com</u>. It can also be obtained by contacting Investor Relations.

Investor Relations: PharmaCyte Biotech, Inc. Investor Relations Department Telephone: 917.595.2856 Email: Info@PharmaCyte.com



Source: PharmaCyte Biotech, Inc.