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PharmaCyte Biotech Moves Closer to Enrolling Patients in Pancreatic Cancer Clinical Trial

Company Aiming to Produce 6-Month Breakthrough Data

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PharmaCyte Biotech (OTCQB: PMCB) is now one step closer to enrolling patients in a pivotal clinic trial in advanced, inoperable pancreatic cancer after the FDA granted its request for a pre-IND (Investigational New Drug) meeting. A host of oncologists, clinicians and scientists that represent PharmaCyte will now sit down with the U.S. regulatory agency to gain valuable insight that will assist them in filing an Investigational New Drug application -- the final step before patients can be enrolled in a clinical trial.

With PharmaCyte and a team of world-renowned oncologists that includes leading pancreatic cancer expert Dr. Daniel Von Hoff from Translational Drug Development (TD2), Dr. Manuel Hidalgo from Harvard Medical School, and Dr. Matthias Löhr from the Karolinska Institute in Stockholm, Sweden, set to begin a clinical trial in the U.S. and Europe, the FDA's IND process is vital to getting there.

After the IND process runs its course, shareholders should be prepared for what a planned 6-month "hard stop" in the clinical trial could bring in the way of data to the industry. If past performance in earlier clinical trials is any indication, PharmaCyte may be a short time away from what could be a very powerful story for patients with advanced, inoperable pancreatic cancer.

PharmaCyte Could Apply for Breakthrough Therapy Designation

The review of data at the 6-month hard stop could very well lead to PharmaCyte's therapy being given the Breakthrough Therapy Designation by the FDA.

A breakthrough therapy is a drug/therapy:

- Intended alone or in combination with one or more other drugs to treat a serious or life threatening disease or condition, and
- Preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

According to the FDA, if a drug/therapy is designated as breakthrough therapy, the FDA will speed up the development and review of the drug/therapy.

PharmaCyte's pancreatic cancer therapy has already received the Orphan Drug Designation from both the FDA and the European Medicines Agency (EMA), so if the company can repeat the data from earlier clinical trials, there is a very good chance that PharmaCyte could earn the breakthrough therapy designation from the FDA as well.

There are two areas specifically that could lead to this designation: (1) quality of life and (2) how well PharmaCyte's therapy can shrink inoperable tumors so that they may become operable. In earlier trials, the company's treatment did improve the quality of life and it did show the ability to shrink a pancreatic tumor.

PharmaCyte Addressing an Unmet Medical Need

PharmaCyte has recognized that there is currently an unmet medical need for patients with locally advanced pancreatic cancer (LAPC) that no longer receive any benefit from using the standard of care for the disease (the combination of Abraxane® plus gemcitabine) after 4-6 months of treatment. PharmaCyte expects that its therapy can meet that unmet medical need. The company will enroll those patients whose cancer no longer responds after 4-6 months of treatment using the current gold standard.

In PharmaCyte's clinical trial, about 84 patients with LAPC will be randomly placed into two equal groups.

- Group 1 will receive just the chemotherapy drug gemcitabine
- Group 2 will receive PharmaCyte's pancreatic cancer therapy

Those who are familiar with PharmaCyte are also familiar with the impressive data from earlier clinical trials where PharmaCyte's pancreatic cancer therapy dramatically outperformed historical data from gemcitabine. In this upcoming clinical trial the company's therapy will go head-to-head with gemcitabine.

PharmaCyte's pancreatic cancer therapy uses the company's signature live-cell encapsulation technology, Cell-in-a-Box® plus low doses of the FDA-approved chemotherapy drug ifosfamide.

The pinhead-sized, porous capsules (Cell-in-a-Box®), which are placed as close to the pancreatic tumor as possible, are filled with thousands of genetically modified cells that act as a type of "artificial liver" in the sense that these genetically modified cells (about 10,000 cells per capsule) are capable of converting ifosfamide from its normally inactive form into its active cancer-killing form -- just as the enzyme system in a patient's liver would normally do.

By moving the conversion site of the chemotherapy drug (from the liver to the Cell-in-a-Box® capsules) closer to the pancreatic tumor, PharmaCyte's therapy can use a lower dose (1/3 the normal dose) of the chemotherapy drug. The benefit to using a lower dose is that it eliminates the side effects normally seen in patients undergoing chemotherapy, and it is the elimination of these side effects that improved the patient's quality of life in earlier clinical trials.

Improved Imaging Should Allow PharmaCyte to Provide the FDA Better Data

Just as Dr. Von Hoff and Dr. Hidalgo worked together on the clinical trials that brought the

industry what is now the gold standard and the FDA approved treatment for advanced pancreatic cancer, Abraxane® plus gemcitabine, so too did Dr. Ron Korn.

Dr. Korn is the Founder, Chairman and Chief Medical Officer of Imaging Endpoints, and just as he was a part of bringing the industry Abraxane® plus gemcitabine, he has signed on to be a part of PharmaCyte's clinical trial as well. This is significant because in earlier clinical trials, PharmaCyte's therapy showed that it could shrink a patients' pancreatic tumor. And, in images posted on the company's website, we see a patients' tumor shrinking dramatically in just 20 weeks (5 months or 1 month sooner than PharmaCyte's planned 6-month hard stop), but that was years ago when imaging wasn't nearly as good as it is today.

Imaging Endpoints will provide PharmaCyte advanced imaging that will help researchers identify biological activity during the clinical trial where traditional imaging fails. So, is there the likelihood that data will show the patients' tumors shrinking even earlier than 5 months and even more dramatically?

Experts from Imaging Endpoints will be involved in training radiologists at all of the clinical trial study sites to ensure the Cell-in-a-Box® capsules are correctly implanted into patients.

Also, Imaging Endpoints will be responsible for coordinating the data obtained from CT (computerized tomography) and PET (positron emission tomography) scans of the patients' tumors as they progress through the clinical trial. Imaging Endpoints will also analyze all of the imaging data obtained during the trial using its state-of-the-art methodology.

The table is certainly set for PharmaCyte's therapy to succeed in the clinic. PharmaCyte's Chief Executive Officer, Kenneth L. Waggoner, has surrounded the technology with the brightest minds in the industry, he's obtained the orphan drug designation for the therapy, the FDA has now granted PharmaCyte a pre-IND meeting and the path to the clinic has narrowed to just getting through the final steps of the IND process. Once PharmaCyte navigates the pre-IND process and files its IND application, then the FDA will have 30 days to make comments, and if no comments are made, then PharmaCyte is effectively "approved" to begin its pivotal clinical trial in advanced pancreatic cancer.

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