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Attaching Chemotherapy Agents to Growth Factors, IGF Oncology LLC is offering hope to Myelodysplastic Syndrome (MDS) Patients with their Lead Drug 765-IGF-MTX now in Clinical Trials at the Mayo Clinic

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CEOCFO: *Dr. McTavish, what was the vision when you founded IGF Oncology LLC?*

Dr. McTavish: I invented our lead drug and founded the company out of my experience as a cancer patient, as chemotherapy was pretty awful. Therefore, primarily I want a better drug and better drugs in general that would be more likely to cure people, but also wanted to spare people the side effects of chemotherapy. The vision was simply more effective cancer drugs with lower side effects.

CEOCFO: *What are you looking at now and what is already developed?*

Dr. McTavish: We have our lead drug 765-IGF-MTX that is in clinical trials at the Mayo Clinic now in a blood cancer called myelodysplastic syndrome (MDS). The results have been very good in the first two patients, so the plan is to continue with that drug and get approval. We have another drug in the pipeline where the IND (Investigational New Drug) application is approved, and we are planning to use that drug for late stage ovarian cancer, for which there is no current treatment on the market. We also have a third drug already in the pipeline that has a somewhat similar design and similar targeting mechanism to the 765-IGF-MTX drug, and that could be in lung cancer or several other types of cancer, but we do not know yet.

CEOCFO: *How did you decide what to tackle first?*

Dr. McTavish: I am a biochemist and in my previous research career I was not very interested in cancer. But after I got cancer I suddenly became very interested. I did a bunch of journal research and wound up getting an experimental treatment that I thought made sense, and then I invented our lead drug as a derivation of and improvement on the experimental treatment I was getting. The experimental treatment worked well for me and had less side effects than when I had conventional treatment and I was cured. Therefore, the experimental treatment worked well, but I thought the drug we have developed would work even better.

CEOCFO: *What is the science behind your drug?*

Dr. McTavish: Our lead drug is called 765IGF-MTX, and it consists of the chemotherapy drug methotrexate attached to our proprietary variant of a protein called insulin-like growth factor (IGF-1). The idea is to target IGF receptors, which are over-expressed on cancer cells. IGF receptors are involved in the biology of cancer because the biological function of IGF-1 is to cause cells to divide and of course that is the problem with cancer cells – that they keep dividing and do not stop. So the drug binds to IGF receptors on cancer cells through the 765IGF protein portion of our drug, and since IGF receptors are overexpressed on cancer cells we get more of the drug to cancer cells and less to healthy cells. That is the

first targeting aspect of our drug. Second, methotrexate has its own selective toxicity for cancer cells. Methotrexate and all chemotherapy drugs act by selectively killing dividing cells. They interfere with DNA replication. That also selectively kills cancer cells because most healthy cells divide less than most cancer cells, so the healthy cells are less affected by chemotherapy. We take advantage of that selective toxicity by using methotrexate as the toxic cargo. However, cancer cells are not always dividing and that is one mechanism by which they survive chemotherapy. IGF-MTX gets around that by causing the cells to divide. Part of the theory of our drug is that when the IGF portion of our drug binds to its receptor on the cell membrane, it causes the cells to divide, thereby sensitizing the cells to be killed more easily by the methotrexate at exactly the time the cell takes up the methotrexate. This means the science is a two-fold targeting affect where we are targeting the drug more specifically to cancer cells, and less of it going to healthy cells, number one, and, number two, causing the cells to divide at the same time they are taking the drug so they are sensitized and can be killed more easily by the drug. Basically, we attach it to a protein and that binds to a receptor on cancer cells, is taken into the cell after binding, and causes the cell to divide, which makes it easier to kill.

CEOCFO: *Has this concept been tried before?*

Dr. McTavish: No, this whole concept has never been tried before.

CEOCFO: *What has been the reception from the medical community who are aware of what you are doing?*

Dr. McTavish: Although many people in the medical community are not aware of what we are doing, the physicians at the Mayo Clinic are excited about it and excited about the results we have had on the first two patients. The people who have looked at it think it makes sense.

“I just tell investors our story. The results with our drug are very good so far and the concept is unique. No one else is attaching chemotherapy agents to growth factors of any sort, let alone IGF.”- Dr. Hugh McTavish

CEOCFO: *Were you looking for something that would work for particular types of cancer or did you develop the drug and then discover where it would be best applicable?*

Dr. McTavish: I developed it initially for all types of cancer in the sense that IGF is involved in many different types of cancer and the receptor is over-expressed in most types of cancers. We picked myelodysplastic syndrome in part because I think the drug may work better in blood cancers than in solid tumors, just because it is hard to get a drug into the middle of a solid tumor. In addition, in our Phase 1, we had our best results in a Hodgkin’s lymphoma patient, which is a type of blood cancer. We picked myelodysplastic syndrome because that is where there is perhaps the greatest medical need of any type of blood cancer. We also found that malignant cells in myelodysplastic syndrome have a high expression level of IGF receptors and they are sensitive to our drug in vitro.

CEOCFO: *What did you learn as the trials have started? What have you found that is different than what you expected?*

Dr. McTavish: In our previous clinical trial we found no decrease in blood cell counts at all, so that was very promising. We kind of expected that from our animal toxicology testing, where we saw almost no decrease in blood cell counts, but we were still pleased to find that in humans. Additionally, that is unique for using methotrexate or any other types of chemotherapy, because that is the most serious side effect of chemotherapy -- that it decreases blood cell counts, a phenomenon called cytopenia. That is the most dangerous side effect, and when patients are killed by the chemotherapy instead of the cancer that is generally the reason they die -- that it decreases their blood cell counts too much. We were very pleased that IGF-MTX did not cause any decrease in blood cell counts, and that had a lot to do with picking MDS as the disease to treat. MDS patients have low blood cell counts as a result of the disease, so they cannot tolerate a treatment that is going to further decrease their blood cell counts. And it has worked as hoped: the two patients treated both had an increase, not a decrease, in their white blood cell counts after treatment with our drug.

CEOCFO: *How did you become involved with the Mayo Clinic?*

Dr. McTavish: It was through our chief medical officer, Dr. Arkadiusz Dudek, M.D. I was involved with him from the beginning of our company, when he was at the University of Minnesota, and we are located in Minnesota. He knew some of the physicians at the Mayo Clinic, so we contacted them about doing the clinical trials there.

CEOCFO: *Are you seeking funding, investment and partnerships?*

Dr. McTavish: Yes, we are seeking both investment and partnerships, as well as licensing to bigger pharma companies.

CEO CFO: *How do you stand out when you are talking with a potential investor, particularly when you are at a conference?*

Dr. McTavish: I just tell our story. The results with our drug are very good so far and the concept is unique. No one else is attaching chemotherapy agents to growth factors of any sort, let alone IGF.

CEO CFO: *How is the concept so different and why has it not been thought of before?*

Dr. McTavish: The more common previous approach used antibodies against receptors, and usually people are interested in turning off the receptor. However, I am interested in turning it on at the time they are taking up the drug, because that sensitizes the cells to be killed by the drug. The receptor activity does drive cancer growth, so the usual thought is we need to turn these receptors off, such as the IGF receptor and the EGF receptor. My thinking was contrary on that, which was to turn them on as the patient is taking the drug. In addition, when people have done drug conjugates it has usually been to antibodies, not growth factors. There are previous examples of toxins attached to growth factors, but not IGF and our approach is different in using chemo agents rather than toxins, which gives us selective toxicity for dividing cells.

CEO CFO: *You have a number of patents. Is that typical or is it because you are a patent attorney and recognize the need?*

Dr. McTavish: It is probably typical to have a number of patents, as everyone in pharma recognizes the need for patents. However, the fact that I am a patent attorney allowed us to get patent work more cheaply than we otherwise would have, which has helped

CEO CFO: *Put it together for our readers. Why does should IGF Oncology stand out from the crowd?*

Dr. McTavish: Number one, I have an interesting personal story in founding the company out of my own experience as a cancer patient. Number two, we have had very good results and the approach is unique of attaching chemo drugs to growth factors in order to stimulate the cells to divide at the time they are taking the chemo agent. Then the bottom line is things are progressing very well in the clinical trials, and most drugs do not work this well in the first portion of clinical trials.