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Issue: January 27, 2025

GlycoMira Therapeutics' First-in-Class, Immune-Modulating Therapeutic GM-1111, Offers Hope in Head and Neck Cancers to Both Protect Healthy Tissue from Radiating Treatment and Reduce the Side Effect of Oral Mucositis

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CEOCFO: ***Dr. Tew, would you introduce us to GlycoMira Therapeutics and your goal as a company?***
Dr. Tew: GlycoMira Therapeutics is a Salt Lake City-based biopharmaceutical firm founded over a decade ago for technology exclusively licensed from the University of Utah. I joined the company in 2015 as CEO, to lead the company from preclinical stage into the clinical arena. Over the years we received over $12 million from the National Institutes of Health to advance our drug candidate to the clinic.

Our lead compound GM-1111 is a first-in-class, immune-modulating therapeutic that also protects healthy tissue from the effects of radiation during treatment of solid tumors. Our goal is to advance GM-1111 through the FDA approval process and to market approval for the treatment of head and neck cancers. GM-1111 has the potential to establish a new paradigm in the treatment of cancer.

CEOCFO: ***So if someone is going in for radiation treatment, there would be fewer complications and worry about healthy tissues being affected by the radiation?***
Dr. Tew: That is true. Head and neck cancer patients receive radiation therapy for five days a week for five to seven weeks. Most head and neck cancer patients will develop moderate to severe radiation-induced oral mucositis during treatment. This is not a trivial or transient side effect. A majority of these patients will develop mucositis beginning as mild inflammation and quickly leading to ulcerative lesions of the mouth. As a result, eating and swallowing become difficult often requiring feeding tubes and narcotic drugs to relieve the pain. Unfortunately, these complications commonly lead to reductions in therapy dosing and treatment interruptions. Presently, treatment options are extremely limited. No drug has been approved to reduce oral mucositis duration, incidence, or severity for patients with solid tumors.

CEOCFO: ***It seems like your compound addresses two modes of action; first is how it is used as an actual cancer treatment in conjunction with chemo and radiation, then its effect on oral mucositis. How exciting! Would you explain?***
Dr. Tew: Yes, our compound has two principal modes of action. One is that it blocks key factors that tumors make to inactivate the immune system. In a sense, it is very much like the immune-modulating drugs that are on the market now.

What makes it unique, however, is that it also quells the oral inflammation that occurs from radiation treatment of the tumor.

In the early stages of our pre-clinical development of this drug, we performed several animal models of fractional radiation to create lesions in the oral mucosa and evaluated the effect of GM-1111 in mitigating radiation-induced oral mucositis. These proof-of-concept studies showed that administration of GM-1111 concurrent with radiation dramatically reduced the occurrence of oral mucositis.

In other models, we implanted human head and neck cancer cells into mice where they would develop into solid tumors. After the tumors had grown, one group was treated with just radiation, another with our drug alone, and a third with GM-1111 in conjunction with radiation. The results showed that GM-1111 was as effective as radiation in reducing the growth of tumors. However, in combination with radiation, the drug essentially eliminated the tumor. GM-1111 is the only First-in-Class anti-tumor candidate that has this type of dual activity.

CEOCFO: ***How is GM-1111 different from other immune modulators that are on the market today?***
Dr. Tew: Immune modulation has been a very important addition to the arsenal of anti-tumor compounds. Basically what it does is make chemotherapy and radiation more effective. The current immune modulators on the market, also known as checkpoint inhibitors, are biological molecules. These biologics have become a powerful new addition to the arsenal of cancer drugs. They are not without some significant issues. There are increasing reports of immune-related adverse events associated with checkpoint inhibitors that can be severe and lead to permanent disorders, and treatment costs are exceptionally high, often exceeding $150K to $200K. Our compound is not a biologic. It is a rather straightforward chemical moiety that is much less expensive to produce and very stable. In extensive animal safety studies, GM-1111 did not have any significant side effects.

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CEOCFO: ***How does GM-1111 work as an immune modulator?***
Dr. Tew: GM-1111 blocks the tumor's ability to produce factors that inactivate the immune system. All immune-modulating drugs minimize the tumor's ability to hide from the immune system. When you can restore an active immune system and then combine it with radiation and/or chemotherapy, you have a much more effective therapy. Our compound is an immune modulator, it just does it by a different method than the biologics, but it has the additional benefit of protecting healthy tissue from the damaging effects of radiation treatment.

CEOCFO: ***How does it protect the healthy tissue?***
Dr. Tew: The standard of care is radiation therapy, despite the dangers inherent in its use. Radiation therapy frequently damages not only the targeted cells in the tumor, but also the surrounding healthy tissue. 50% of all tumors are treated with radiation. This can create an unwanted severe inflammatory condition in the tissue surrounding the tumor that can often limit the success of therapy. Our drug significantly reduces inflammation and modulates the immune response, protecting the healthy tissue near the tumor during radiation therapy.

CEOCFO: ***Where are you in the process?***
Dr. Tew: We had a decade of pre-clinical development to understand the compound and its applications. We have completed all of the FDA's required pre-clinical animal safety and toxicology studies. We recently filed an Investigational New Drug application, (IND) with the FDA, for Phase 1a first-in-human clinical studies.

The FDA has thirty days from receipt of our IND to review our information, to ask questions, and at the end of thirty days they have a choice. The choice is to let us proceed to the first phase of human trials or impose a clinical hold while we resolve any other outstanding issues. Clinical holds are not particularly bad; sometimes a little more time is needed to answer the Agency's questions.

CEOCFO: ***Where will these studies be taking place?***
Dr. Tew: Phase 1 clinical investigations will be done at the Massey Cancer Center, at Virginia Commonwealth University (VCU), Richmond Virginia. The Phase 1a studies will involve twenty to thirty patients to determine the maximum tolerated dose and examine safety in humans. Larger Phase 1b clinical trials enroll up to 40 head and neck cancer patients and look for indications of efficacy along with the physiologic effects of the drug on the human body. It will take about two to three years to complete those studies.

If the Phase 1 clinical trials are successful as we expect, we will seek a partner or licensee to take this drug into Phase 2 clinical trials and look at a larger patient population and more evidence for efficacy. Phase 3 trials are much larger, looking for statistical significance of efficacy. The overall development program from now until the time that the drug would be eligible for market approval could be five to seven years.

CEOCFO: ***Has anyone tried to use this compound before GlycoMira?***
Dr. Tew: This compound was created by researchers at the University of Utah. It did not exist before that. GlycoMira holds worldwide license rights to that compound. Our patent portfolio continues to grow with the addition of new therapeutic applications of our technology.

CEOCFO: ***Are there other cancers that GM-1111 may someday be used to treat?***
Dr. Tew: The tumor suppression effects of GM-1111 are not limited to head and neck cancers but are also demonstrated in other cancer models. In multiple tumor models, GM-1111 alone reduced tumor growth and inhibited cancer stem cell proliferation in colorectal, lung, renal, and breast cancers and in organoids derived from cancer patient biopsies. GM-1111 alone and in combination with chemotherapeutic agents was statistically superior to chemo-agents alone in inhibiting the growth of endometrial, lung, and colon cancers.

CEOCFO: ***Drug development is expensive. Where are you with funding?***
Dr. Tew: We are going to raise money. Our CFO, Kenneth R. North is the key person. We have some interest, but as you can imagine, nothing is going to happen until we get an FDA approval for clinical trials. We expect that to come within the next three weeks or so. Once we have that, then there will be a concerted effort to bring in the funding to do the Phase 1A studies. As they progress and are looking successful, then we will seek additional funding for the 1B studies.

The approval process through the FDA is many years and many tens of millions of dollars. Presently we are only approaching the Phase 1, first-in-human study to establish safety and establish the maximum tolerated dose in humans. The Phase 1a trials will cost approximately $2M.

CEOCFO: ***Clearing reasonable risk is the key with the FDA for in human trials.***
Dr. Tew: Clearing reasonable risk depends a lot too upon the disease indication. If this was a drug for glioblastoma, a brain tumor, which is 100% fatal, the bar for safety in human clinical investigations is fairly low for a chance at prolonged life. For a drug for something like high blood pressure, which people can live with, then the bar for safety is quite high. We think our bar is someplace on the lower side. Head and neck cancer are very aggressive and difficult to treat, and hopefully, GM-1111 will give these people longer lives and in some cases remission.

CEOCFO: ***What is the takeaway for people in the medical and investment communities?***
Dr. Tew: This is exciting. Anytime you push back against the frontiers of darkness, it is a challenging road. There is no shortcut to drug approval. We have strong pre-clinical data and animal data. What counts is what it does in humans. The drug development world is a proverbial graveyard of products that looked good in the beginning but for some reasons did not work in humans. The only thing one can do is go forward with optimism, good science, and good studies. We will see what happens. The FDA is very keen on exploring new oncology therapeutics, with reasonable assurance that they are safe. What they will be looking for in our first Phase 1 is evidence that you are not putting patients at unreasonable risk.