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Novel, Radio-Labeled Peptide Development for Metastatic Melanoma Treatment



Les Stewart
President
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"Metastatic melanoma is on the rise with few treatment options and no cure. SolaranRx offers a unique mechanism of action for treating metastatic melanoma that has the potential to be efficacious, cost effective, and more palatable for patients."- Les Stewart

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CEOCFO: Mr. Stewart, what is the concept behind SolaranRx?

Mr. Stewart: Advanced melanoma is among the most aggressive forms of cancer with an average survival rate of six months and a one-year mortality of 75 percent. SolaranRx is developing a novel, radio-labeled peptide for the treatment of metastatic melanoma.

CEOCFO: What is the standard treatment for metastatic melanoma now and how is your technology different?

Mr. Stewart: First, metastatic melanoma is challenging to treat and there is no cure. Standard treatment has evolved significantly over the last three years from chemotherapy to a new class of drugs called immunotherapies. These are an improvement over chemo, yet only a limited number of patients respond and many experience serious, sometimes fatal, side effects. Immunotherapies manipulate the immune system in an attempt to fight the cancer. In contrast, our radiopharmaceutical has a completely different mechanism of action. We deliver targeted radiation directly to the melanoma tumor through our novel peptide that binds to a unique receptor overexpressed on melanoma, known as MC1. Data suggests that 80 percent of human melanoma samples have the MC1 receptor, allowing our peptide to deliver highly targeted radioactive therapy to the tumors with minimal impact to healthy cells and fewer side effects. This is a major advantage to the patient and more cost effective to the healthcare system.

SolaranRx's lead product, SRX-1177, is a theranostic, which combines therapy and diagnostics with the same drug. In the diagnostic use, the patient first receives a low dose to determine if they have the targeted MC1 receptor. If this is the case, patients receive a stronger, therapeutic dose of the same drug that delivers targeted radiation to the melanoma tumors with minimal impact to surrounding healthy tissue. This ability to identify suitable patients quickly is important, as time is the enemy for patients with melanoma. Good candidates can be treated and others can move rapidly to other therapies.

CEOCFO: *What is the background of developing this particular peptide?*

Mr. Stewart: The technology has been developed over ten years of research at the University of Missouri and the University of New Mexico. The inventor, Dr. Yubin Miao, is currently at the University of New Mexico and has published nearly 20 articles in peer-reviewed biomedical journals demonstrating *proof of concept* in animal studies. This attracted us to the technology and the lead molecule. It shows high tumor uptake and very low non-tumor binding with fast excretion—all desirable traits. We're ready for clinical trials once we scale up our manufacturing and complete IND enabling studies.

CEOCFO: *Is the medical community aware of your technology yet, or is it too early?*

Mr. Stewart: It is still a little early since we're in the pre-clinical stage. We will command more attention once we develop clinical data in patients. Nevertheless, everyone recognizes the still-unmet medical need and we have been getting a lot of traction from potential investors and partners who see the benefits of our technology. The metastatic melanoma market is currently \$1 billion globally and is projected to grow to \$4.4 billion by 2022, indicating a lot of opportunity. SolaranRx is well positioned to be a part of it.

CEOCFO: *What is your timetable?*

Mr. Stewart: We are currently raising funds for an exploratory clinical study to demonstrate receptor targeting of our lead product, SRX-1177, in metastatic melanoma patients. Once we're funded, we'll need 18 to 21 months to reach that value inflection milestone. Following that, we will conduct a Phase 1/2A clinical study for safety and preliminary efficacy with a therapeutic dose, requiring about two years. This will be a significant value inflection milestone demonstrating the potential of SRX-1177 to help patients.

CEOCFO: *Will you be looking for partnerships or are you going it alone?*

Mr. Stewart: We are open to partnering as long there's strong alignment on goals and strategic interests. We have identified a number of early partners, such as manufacturing and contract research organizations but we are also looking at strategic alliances with larger companies for development, commercialization, and potential equity investment. Discussions are at an early stage, so our options are open at this point.

CEOCFO: *What have you learned over time that is most helpful here in positioning?*

Mr. Stewart: You must have a clearly defined unmet need in the market coupled with novel, outstanding science capable of responding to that need. We believe our peptide and its application to metastatic melanoma is very strong. Our mission now is to validate our technology in a clinical setting and advance it through the different stages of development and

ultimately commercialization. If you can marry unmet need and proven science with the right financing and the right partners, your chances of success are exponentially greater.

CEO CFO: *Are you aware of what your competition is considering?*

Mr. Stewart: Because of the tremendous unmet need in metastatic melanoma and the growing market, many large pharma are developing technologies, especially immunotherapies, and bringing them to market. However, I have not seen any radiotherapy solution like ours for metastatic melanoma—although favorable clinical results have been shown using radiotherapies to treat other cancers. Radiotherapeutics for metastatic melanoma is novel and differentiates us, creating a unique opportunity for SolaranRx to lead in this area.

CEO CFO: *Will there be potential for treating other types of cancer?*

Mr. Stewart: This particular peptide targets a receptor over-expressed only in melanoma, leaving out other cancers, *per se*. Our initial indication is focused on unresectable stage III and stage IV melanoma. We also see expansion into adjuvant therapy for patients with earlier stage melanomas who have a high risk of re-occurrence.

CEO CFO: *SolaranRx was recently named among the “Top 10 Most Interesting Oncology Projects to Watch” for 2014. How were you able to get that honor and what does it mean in terms of interest and financing for the company?*

Mr. Stewart: That's a great story. Each year, Kantar Health and Informa engage an independent panel of experts to screen hundreds of products using very rigorous criteria. These include unmet medical need, market potential, diversity of indications, strong science, partnering opportunities, and potential for new opportunities beyond initial indications. Products selected among the “Top Most Interesting Oncology Projects to Watch” have met the criteria and represent what Informa and Kantar Health consider among the most attractive opportunities the industry has to offer. We were honored to have SolaranRx's lead product selected and it certainly opens doors for us. For example, we just returned from Boston where we received this honor and presented our technology. We made contact with interested strategic pharma companies and potential partners to assist in our fundraising activities. This meeting definitely gave us credibility and showed how our unique platform is compared to other products on the market or in development.

CEO CFO: *Put it all together. Why SolaranRx?*

Mr. Stewart: Metastatic melanoma is on the rise with few treatment options and no cure. SolaranRx offers a unique mechanism of action for treating metastatic melanoma that has the potential to be efficacious, cost effective, and more palatable for patients. We have one patent issued, one that just received an allowance to issue, and two other patent applications in-process. Our ability to go after a very large unmet need with proven science is an exciting proposition for patients and their physicians who have far too few options for treating metastatic melanoma.

Interview conducted by: Lynn Fosse, Senior Editor, CEO CFO Magazine
