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Q&A with Eboo Versi, MD PhD, Founder and Chairman of Dina Pharmaceuticals, Inc. developing a *New* Approach to treating Parkinson's Disease with a Small Molecule DAMA Compound Targeting the Encephalin Receptor that shows promise in treating the very debilitating Levodopa-Induced Dyskinesia Side Effect and works as a Stand-Alone Therapy

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CEOCFO: ***Dr. Versi, what is the vision behind Dina Pharmaceuticals?***
Dr. Versi: We want to provide a novel therapeutic for patients with Parkinson's disease. We are targeting the worst aspect of the disease, that is people who cannot tolerate levodopa and so are looking to have expensive and potentially dangerous deep brain surgery.

CEOCFO: ***What is your approach?***
Dr. Versi: We have a novel new chemical entity small molecule drug that has a dual DAMA action. DAMA stands for **D**elta **A**gonism, **M**u **A**ntagonism. All of the therapies that are currently available for Parkinson's disease relate to the dopamine axis including levodopa which is the precursor of dopamine. We know that Parkinson's disease is due to degeneration of the dopamine containing neurons in the substantia nigra but by the time a patient presents with symptoms, they have lost half of those nerve cells. Therefore, the Gold Standard treatment is to treat with levodopa and that works fabulously. However, the problem is that after 3 to 4 years, its utility diminishes, and serious side effects develop such as dyskinesia. Parkinson's patients tell me they feel that at times, dyskinesia is worse than the actual disease. This levodopa-induced dyskinesia (LID) is characterized by involuntary, non-rhythmic, purposeless, and unpredictable movements which are severely disabling, make patients miserable and LID significantly increase treatment costs. Other therapeutic approaches either alter the way it is given, or use a drug that is very similar to the way levodopa works (dopamine agonist). All these approaches target the so-called "direct pathway" or nigrostriatal pathway. Our approach is different.

CEOCFO: ***Would you explain how this works?***
Dr. Versi: Downstream from the dopamine pathway is the secondary or indirect pathway that send signals from the striatum to the globus pallidus in the basal ganglia of the brain. The neurotransmitter that is responsible for this is a peptide called encephalin and this is important in Parkinson's disease as the body tries to compensate by up-regulating this secondary pathway. Dina Pharma is targeting this indirect pathway by developing a small molecule DAMA compound called DPI-289. This drug could be used on its own, or in combination with levodopa, to achieve an even more potent and lasting effect.

CEOCFO: ***What does your drug do in the body?***
Dr. Versi: DPI-289 augments the indirect pathway by acting on the delta receptor that is the encephalin receptor, thus allowing the patient to be able to move normally. The drug also acts against the mu receptor which prevents the onset of LID and it may even reduce LID.

CEOCFO: ***Where are you in the development process today?***
Dr. Versi: We are now ready to do the IND enabling toxicology studies that are needed before we can start FDA approved human trials. We plan to initially develop the drug for ameliorating LID. To date we have no indication that there are any safety problems with our drug.

CEOCFO: ***What have you learned from the animal trials?***
Dr. Versi: We have learned that the effect of the drug in combination with levodopa was synergistic and even more profound than when it was used alone suggesting that doctors could use DPI-289 in both ways. Patients with Parkinson's disease who are having difficulty with the terrible symptoms of LID and finding it difficult to tolerate levodopa could, with the help of our drug, reduce their dose of levodopa to a more tolerable level without becoming more Parkinsonian, the so called, "Dopa Sparing Strategy".

CEOCFO: ***What has been the reaction of people in the medical community that may know what you are doing?***
Dr. Versi: We have presented this data at Neuroscience and International Movement Disorder Society conferences, and we have seen a very positive response. Just in the last couple of weeks we've had our work published in Neuropharmacology, a very prestigious peer reviewed scientific journal. I have to say that we have been very fortunate in having received a grant from the Michael J. Fox Foundation to fund this work; it was for $1.5 million. Our strategy initially was to only go for non-dilutive funding in the form of grants, which is what we have done so far. We have also applied to the NIH, so we are waiting on that. However, we now feel that we are ready for prime-time, which is to actually get dilutive equity based funding to move the program forward more quickly.

"Our mission is to address a major unmet medical need in Parkinson's disease and we are unique in utilizing the DAMA approach. In contrast to other pharma companies, we have no debt and our long lasting intellectual property is not liable to royalty payments. We are virtual and "lean and mean" as we want the maximum number of cents in the dollar to advance development, rather than spend on salaries and G&A. Therefore, we are an attractive investment opportunity with a potentially huge return for a small investment."- Eboo Versi, MD PhD

CEOCFO: ***What do you understand about the investment side? How will you go about getting the attention you need?***
Dr. Versi: We need to raise up to $25 million over a period of five years to get to the end of Phase 2/3 which would be one study away from FDA approval. On the way, a raise as small as $650,000 would allow us within 9 months to do the formulation development, which will generate additional patents and so add value. We also think that our best way forward is to go for an Orphan Indication, because when patients come to the end of their levodopa days, they have a choice to either suffer or go for deep brain stimulation, which is extremely expensive from a payer point of view and also pretty invasive from a patient's point of view. It is not a cure and comes with many complications and the need for repeat surgery to periodically replace the battery. We want our drug to reduce or prevent invasive brain surgery, a very good value proposition that would command premium pricing. However, once doctors are familiar with this drug being used in combination therapy, they are likely to try it as monotherapy and then of course we would apply for broader FDA indications.

CEOCFO: ***Where did the idea for your technology originate?***
Dr. Versi: Originally the technology came out of the Burroughs Wellcome Group; DPI-289 is the latest iteration. They were working on creating a library of small molecules that would impact the delta opioid receptor. When one hears the word, "opioid" one thinks of pain, but there are three G protein-coupled receptors, mu-, delta-, and kappa, which are stimulated by a family of endogenous opioid peptides collectively called endorphins. While stimulation of the mu receptor is necessary for strong pain relief, the other receptors are involved in a variety of other important effects in the body. In our particular situation, DPI-289 would have no effect on pain, because it inhibits rather stimulates the mu receptor. That also means it does not have the negative effects of opioids such as respiratory depression and abuse liability. The science started there, but it kind of evolved as there was good data that suggested this drug would work for depression. Depression is a very difficult thing to crack from a regulatory point of view, and I thought that perhaps we could look at DPI-289 for Parkinson's disease, because we knew delta agonist are effective in animal models of Parkinson's disease. Incidentally, this drug could still work for depression, and as half of patients with Parkinson's disease also have depression, this could be an opportunity to avoid polypharmacy in the elderly.

CEOCFO: ***You mentioned Orphan drug status, but it seems that Parkinson's is quite common or is it that it gets more attention than some other diseases?***
Dr. Versi: You are right. It is estimated that there are about 1 million people with Parkinson's in the United States, but actually only about half are diagnosed. The FDA mandates that there have to be less than 200,000 patients in the US, for a drug to be eligible for Orphan designation. They also say that within a disease category, a subset could be defined for Orphan designation, so when we are targeting levodopa refractory patients who would otherwise have to have deep brain stimulation, that population is well under 200,000. Consequently, we are very confident we will get that designation.

CEOCFO: ***Put it together for our readers. We reach many people in healthcare, as well as the investment community. With so many new ideas to consider how does Dina Pharmaceuticals stand out?***
Dr. Versi: Our mission is to address a major unmet medical need in Parkinson's disease and we are unique in utilizing the DAMA approach. In contrast to other pharma companies, we have no debt and our long lasting intellectual property is not liable to royalty payments. We are virtual and "lean and mean" as we want the maximum number of cents in the dollar to advance development, rather than spend on salaries and G&A. Therefore, we are an attractive investment opportunity with a potentially huge return for a small investment.