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Disease Modification of ALS, Parkinson's Disease and Ischemic Stroke

***Winston Ko** - CEO*

About Genervon Biopharmaceuticals LLC

- Genervon has discovered and developed a new class of "master regulator" bio-drugs that develop, protect and correct the human nervous system.

- In the past year, Genervon has been conducting three Phase II trials for amyotrophic lateral sclerosis ("ALS"), Parkinson's disease and ischemic stroke.

- Genervon recently successfully completed its Phase IIa clinical trial for ALS. A full analysis of the trial's result is expected to be completed soon. But preliminary data suggests that Genervon's novel, proprietary, multi-target biological drug candidate, GM604, shows significant promise for treating ALS.

- Following the completion of six doses of GM604 over two weeks, treated ALS patients were evaluated 10 weeks later without further treatment. In seven out of eight ALS patients treated with GM6 the preliminary clinical measurements of ALS disease progression have slowed or stopped.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: ***Mr. Ko, it has been about a year since we have spoken. What have been the highlights over the past year at Genervon?***
Mr. Ko: Over the last year, we have been conducting three Phase II clinical trials for disease modification of ALS, Parkinson's disease, and ischemic stroke.

We have just locked the data and unblinded the randomization code of our ALS trial. For the Parkinson's disease trial, we are currently enrolling the last patient. For ischemic stroke, we have enrolled 27 patients and there are nine more patients to go. We expect to finish all three Phase II trials soon and we hope to announce the results by the fourth quarter.

CEOCFO: ***What next?***
Mr. Ko: We are planning the next clinical trial for ALS based on what we have learned from Phase IIa. We are also ready to collaborate with one or more pharmaceutical companies to finish the trials and to apply for new drug approval (NDA) for all three and for future indications. I would rather have my partners take care of sales and distribution. Medical science and drug development is more fun for me.

CEOCFO: ***Is it a bit unusual to have so many trials going at once?***
Mr. Ko: Yes it is.

CEOCFO: ***How are you able to organize all of this?***
Mr. Ko: We have a great team plus many of our trusted external contract research organizations (CROs). All three trials are with different principal investigators, different medical institutions and different sets of CROs. There is a great deal of work, but we have confidence in our investigational drug GM6 and that is why we go for all three trials at the same time.

CEOCFO: ***How important is it to choose the right trial company? How do you choose the right people to conduct the trials?***
Mr. Ko: For these three trials, Genervon has been managing them. I wanted better control over the quality and the speed of the trials. I want to thank my team plus a dedicated team of specialty CROs.

CEOCFO: ***What have you learned along the way that allows you to do this yourself?***
Mr. Ko: Dedicated people love to get things done efficiently. There is professional pride in a job smartly done. But it requires strong leadership. My team and CROs are always pleasantly surprised that they get answers and direction from me within hours of asking a question.

CEOCFO: ***What is the basic concept at Genervon?***
Mr. Ko: The classic drug development model in the industry is a single-target drug development mindset. However, the human body is a complex and interconnected organism, especially in the case of nervous system disorders and diseases.

It is difficult to design even one molecule that can attack a single target. Nobody is smart enough to design a molecule that can be effective and can attack multiple targets simultaneously and dynamically.

The human body's many biological systems work in harmony with the help of many levels of endogenous regulators. In the 1990s, we set out to find the highest level of endogenous early stage master regulator of the nervous system as a multi-target drug candidate.

CEOCFO: ***What have you found and developed?***
Mr. Ko: We found GM6, which has the highest expressed at week 9 of human pregnancy. It is an endogenous embryonic/fetal stage master regulator for the human nervous system. It regulates a wide array of cell functions, from differentiation to apoptosis. It is important in an array of biological processes including embryonic development, anti-inflammation, anti-oxidation and neuro-regeneration. It is a transcription factor involved in differentiation of ectoderm cells in the embryo into the human nervous system and epidermis. It took us a long time to develop GM6 into a Phase II drug candidate.

"In seven out of eight ALS patients treated with GM6 the preliminary clinical measurements of ALS disease progression have slowed or stopped." - Winston Ko

CEOCFO: ***Why does it take so long?***
Mr. Ko: Well, that is the nature of medical science. For example, when we cut the sciatic nerve of several hundred rats in a series of experiments testing GM6, it took us over three years to watch the nerve grow back and count all the regenerated motoneurons. The mice in NIH's Wobbler mice model for motoneuron disease would die in less than three months. We were confident that the treated mice would live for at least four months. But they ended up living for more than a year. That is very good news. The bad news is that this one experiment caused delayed for almost a year in our other sequential experiments!

CEOCFO: ***What did you learn in Phase I or II that has altered what you are going to do in Phase III?***
Mr. Ko: We learned from Phase I that GM6 is very safe at multiple maximum tolerated dose levels. It was very comforting to confirm that a neural drug that can pass through the blood-brain barrier at a very high and multiple doses is safe and tolerable.

Clinical trial data is what it is. We learned that we have to double our training and monitoring efforts to ensure the best quality data collection.

CEOCFO: ***In March, you were granted "orphan drug" status for the ALS disease indication; would you tell us about that?***
Mr. Ko: GM6 was granted both the "orphan drug" and the "fast track" designation for ALS. True to their promise, the FDA has been very supportive and cooperative. They gave us a very expeditious investigational new drug (IND) approval in less than thirty days. We will seek their counsel as we develop the next trial and all the way to the drug approval.

CEOCFO: ***Is the medical community paying attention?***
Mr. Ko: We receive many emails from doctors asking for our investigational drug because they have patients who are dying without viable treatment options. However, we have to wait for the FDA's approval before we can give them the drug.

CEOCFO: You are closer than you have ever been, but it is a long and arduous process!
Mr. Ko: Indeed it is. Granted we did not know what we were getting ourselves into at the beginning. The discovery and development of new drugs are probably one business that takes the most time and financial commitment. But we have accepted the challenge in response to the suffering patients especially in the aging population. We've stayed as a privately held company in order to move our work forward faster.

CEOCFO: ***Are there other companies focusing in the same area or are you in a class by yourself?***
Mr. Ko: Every pharmaceutical company loves to be in the central nervous system (CNS) space. But there have been decades of futility in this space in terms of drugs approval-for CNS disease modification. We are a new kid on the block who happened to believe in a new paradigm for multi-target drug discovery and development.

CEOCFO: ***Do you find it surprising that science has not reached the point of understanding what you do?***
Mr. Ko: I am not surprised and do not take it personally when the establishment is skeptical of a maverick like me. The whole ecosystem of medicine has a life of its own. I hope it will find out soon that I am here to help. My goal is not to threaten the established order. I simply responded to the suffering of patients with life threatening diseases. Disruptive innovations do generate renewal and disruption at the same time.

CEOCFO: ***Why pay attention to Genervon?***
Mr. Ko: There are many entrepreneurs creating disruptive innovations in California, not only in high-tech areas, but in the biopharmaceuticals sphere as well. I am just one of them. My team and I are delighted that we have discovered and developed an innovative new class of breakthrough bio-drugs.

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