

Moon Eun-Sang - CEO, Sillajen - South Korea



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Sillajen's CEO shares his passion for his companies oncolytic vaccinia virus, and its potential to revolutionize the treatment of solid tumor cancers, even arguing that it may eventually constitute 'a cure for cancer'.

Could you please introduce yourself Dr. Moon, and tell us how you became involved with Sillajen?

I am a double licensed dentist and medical doctor, and completed my studies at Seoul National University and the Moscow medical school respectively; my specialty is maxillofacial rehabilitation, or head and neck surgery. While I still practiced, I was an investor in Sillajen and followed Jennerex's oncolytic vaccine project, Pexa-vec, with great interest as I thought it had an incredible amount of potential. When the project stalled due to financial difficulties at Jennerex, I decided to become involved with the project more directly so I closed my clinics and took over as the CEO of Sillajen.

How would you assess the potential for Pexa-Vec, your lead-product candidate?

The truth is that it is a bona fide medical breakthrough of immense proportions, one that will bring about great benefits for humanity. A lot of people involved in the project couldn't believe what we were doing at first, but the truth is that Pexa-Vec doesn't represent just a cancer treatment, but an actual cure for cancer. The vaccinia virus we have engineered will seek out cancerous cells, infect

and destroy the cells, but not before reproducing and spreading to other cancer cells, and triggering a strong immune-response from the patient. In our phase II A trial, out of 30 patients, 21 demonstrated partial tumor responses, and four were completely cured. More than ten percent of the patients were cured which is truly incredible, especially given their prior prognosis. At present, we are preparing to begin a global phase III clinical trial for Pexa-Vec's efficacy as a treatment for hepatocellular carcinoma (HCC).

There are a few companies that have been involved with Pexa-Vec project previously, how did Sillajen end up in control?

The project originated as a collaboration between Jennerex, a California based biotech venture, and scientists at Pusan National University, as well as Dong-A University. At the time, Sillajen was just a small CRO with modest laboratory capabilities that worked on the project starting in 2006. Also, it is important to recognize that we were involved with the earliest stage of research activities related to Pexa-Vec, much of which had been carried out in Korea, ranging from toxicology and pharmacokinetic tests, to animal testing and phase I clinical trials. Once Pexa-Vec reached phase II, we started conducting trials worldwide.

In late 2013, a Phase II B clinical trial for Pexa-Vec failed to meet its overall survivability endpoint, and Jennerex lacked the capital to continue development without a new investment. Many of the existing investors were quite discouraged by this failure, which made it an ideal moment for Sillajen to step in and take a stronger financial position in the company, and since we had been carrying out the research activities for Pexa-Vec for so many years, it was clear to us that the trial failure was not indicative of Pexa-Vec's potential. This was the point in time where I stepped in, and managed to raise USD 150 million from Korean investors to fund our acquisition of Jennerex.

Why were you confident that the trial failure wasn't a negative sign for the drugs potential?

The phase II B trial results were unfortunate but avoidable. Ironically, the phase II A results were so strong, so marvelous, that some of the doctors conducting our trial were very excited and became somewhat aggressive in their patient recruitment, choosing a number of patients in the very late terminal stage. As a result many of the patients didn't survive long enough for the Pexa-Vec to take effect, and moreover, out of the 86 patients recruited, 30 percent didn't survive long enough to get a second injection, when our treatment protocol calls for series of six injections. Thus, we see this failure as a failure of the trial and the trial design, not of the candidate; the same patients may have responded well to Pexa-Vec if their treatment had begun sooner. As we move forward with

our phase III HCC trial, we are very confident that Pexa-Vec will meet the expectations set by the phase II A trial.

A number of other companies are developing oncolytic vaccines using other viruses; why is a vaccinia-based virus so revolutionary compared to these others?

For reference, vaccinia virus infects internal organ tissue cells, and therefore can be engineered to attack cancerous organ tissue, which includes most forms of solid tumors. The other oncolytic products in development use other viruses, such as the herpes-simplex virus that infects skin and mucosa cells, or HIV, which attacks blood cells, and thus can be used to fight skin and blood cancers. We are the first company to try to develop an oncolytic vaccinia virus.

Of the viruses that could be used to fight solid tumors, the team working on this project decided back in the early 2000s that the vaccinia virus was the best after a long series of tests in which it outperformed adenovirus and herpes-simplex, among others. Apart from its ease of use as a biotech platform, the primary advantage is that it we can deliver the vaccinia virus to tumors intravenously as well as intratumorally, while the other oncolytic candidates that are suitable for solid tumor cancers must be injected intratumorally.

Given your current pipeline, what is your current vision for Sillajen as a mature company?

Well, my vision is that we will lead a medical revolution. The cure for cancer is not science fiction; we have completely cured patients with a wide variety of cancers, spanning from hepatocellular carcinoma (HCC), recurrent HCC, breast cancer, melanoma, colorectal cancer, renal cell carcinoma, nearly 10 percent of all of those that we've treated. There is still a lot of work to be done, and we are now trying to find the common factor between the patients that we've been able to cure so we can understand why they responded so strongly while others didn't. We are also working on more advanced versions of our oncolytic vaccinia viruses that are somewhat immune-resistant, allowing them to attack the cancer cells for longer and lowering dosage requirements, and that are engineered to target specific tissue types more precisely so that they can be delivered more effectively to the tumor cells.

How do you feel personally about playing a part in creating a "cure for cancer"?

I lost my family to cancer, so I know how painful and how much suffering a person goes through in the late stages. That is the reason that I switched jobs. I truly do believe that we are working on something revolutionary, as significant of a medical breakthrough as penicillin. Just as penicillin, a

fungus, is the natural enemy of and a magic bullet for bacteria, I think that vaccinia, a virus, can be the same for cancers. Vaccinia virus is truly a gift from god; it already helped to cure the world of smallpox, and now it is well on the way to curing cancer.

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