Kyoung-June Lee â?? CEO, JW CreaGene, South Korea

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oung-June Lee, CEO of JW CreaGene, lifts the lid on their novel technology of developing an immuno-oncology treatment from dendritic cells, which act as a command centre of the immune system in the body. He also assesses how this new treatment will compare to existing technologies, such as CAR-T.

Can you introduce yourself and JW CreaGene to our international readers?

Since becoming part of the JW Group in 1989, I have been involved with drug development. In 2004, I moved to the C&C Research Laboratories, which is a collaboration between JW Group in Korea and Chugai Pharmaceutical Co. in Japan. In 2015, I was promoted to the director of Drug Discovery Centre at JW Pharmaceutical and to a CEO at JW CreaGene.

The JW Group originally started with a focus on small molecules and had plans to expand in this field. However, lately, we felt the need to develop immune-cell therapy, because small molecules have drawbacks that might cause problems regarding their side effects. Our immune system, on the other hand, is using part of our own body, so we started considering how we can utilise this as part of a treatment. For this reason, the JW Group merged JW CreaGene into a subsidiary company of JW Shinyak to develop immune-cell therapy in 2009.

JW CreaGene is under the JW Group with healthcare-oriented goals. JW CreaGene was established in 1998. During the last two decades, we developed and possessed the core technologies needed for dendritic cell therapy including dendritic cell generation, antigen delivery system, and protein engineering. Based on these technologies, we generated patient-customized dendritic cell therapeutics, called CreaVax, and are conducting clinical trials for various tumour treatment.

What is the potential for dendritic cell treatments, and how does it compare with other immuno-oncology therapies such as CAR-T?

The dendritic cells act as a command centre of the immune system in the body. Dendritic cells exist in mucous membrane of skin, nose, lung, stomach or intestine that is easily exposed to the external environment and are also observed in blood. These cells provide information on the antigens to T cells to control the immune reaction by activating or inhibiting antigens-specific immune reaction. That is, dendritic cells are the most potent antigen presenting cells that induce and proliferate the

specific immune cells for the disease-associated antigens.

When we began our research, immunotherapy was rarely applied in the field. Recently, the importance of immune reaction has been proven by the approvals of the immune checkpoint inhibitors such as Keytruda or OPDIVO, and genetically modified T cells such as CAR-T. However, these therapies have side effects such as cytokine release syndrome (CRS), neurotoxicity, as well as limitations including complexity of manufacturing process and limited disease treatment, only for leukaemia.

Dendritic cells utilize the cells isolated from our own body, taking them out from the body and injecting them back with a bit of manipulation, so there is no risk or side effects regarding immune responses. Dendritic cell therapy also has advantages compared to other immune-cell therapy. First, since dendritic cells are also involved in generation of memory cells as well as induction of tumour killing effector cells, these can provide the long-term protection effect to patients. Secondly, since dendritic cells are well tolerated and safe in the body, the therapy has high potency as a combination therapy with other treatments.

What is your vision for the company?

Our main objective is receiving approval for our products from the Korean government to launch them in Korea as soon as possible. We have five product pipelines for dendritic cell targeting various cancers and autoimmune disease. Among them, our product for liver cancer treatment, called CreaVax-HCC, is in phase III trial. The target patient stage of the treatment is stage A-B, where the patient can be operated on; the dendritic cell treatment can suppress recurrence. We already have approval for our product to treat renal cell carcinoma (CreaVax-RCC) as an export medicine. We also have a product which treats glioblastoma multiforme (GBM), a very fatal disease. This therapy (CreaVax-BC) is under phase I/II trials for patients already receiving chemoradiotherapy. Furthermore, we have a plan to expand our product pipelines to other cancer forms in the near future.

We are looking for global partners to enter overseas markets. For the reason, we hope to conduct clinical trials in other countries including USA, Japan, Vietnam and China after approval in Korea.

How much interest is there in the development of dendritic cell treatments?

The first-generation of dendritic cell company is Dendreon. They received approval for their first product for prostate cancer treatment, called Provenge, by FDA. There are other companies including Northwest Biotherapeutics and Argos Therapeutics. Recent trends in immune cell therapy are mainly focusing on the development of adoptive T cell therapies including CAR-T, because these therapies showed successful therapeutic effects despite the aforementioned their side effects. For this reason, dendritic cell companies, including JW Creagene, are developing various way to improve the dendritic cell function leading to a generation of more powerful antigen-specific T cells such as combination therapies between dendritic cell and other treatment.

The government has an objective to turn Korea into an innovation hub. What is the potential for this to be realised?

I feel very positive about the idea and am taking a positive approach. However, the fourth industrial revolution is not just about the treatments available, but also diagnostics. The Korean government is increasing the R&D investments on new drug development. Recently, some Korean pharmaceutical companies have achieved remarkable results with technology and drug exports including Hanmi, Yuhan and JW. It has proven that Korean companies have global competitiveness.

JW CreaGene has been focusing on R&D of treatment to prevent the recurrence of some types of cancer. Until now, JW CreaGene has performed several government-sponsored tasks. Government agencies such as KFDA (Korea Food and Drug Administration) and KHIDI (Korea Health Industry Development Institute) are providing strong support for the new drug development. As Korea becomes a bio-innovation hub, we will soon be contributing to show performance.

What are your ambitions for the next 3-5 years for JW CreaGene?

Most of all, I would like to get an early approval for our clinical trial products so that cancer patients can benefit quickly. In addition, we are currently considering the identification of specific neoantigens for various types of cancers, based on genetic profiles. Some people have genetic mutations to be expressed in cancers. Our idea is to design a cancer vaccine using dendritic cell loading newly identified neoantigens. We will be also trying to find the optimal combined counterpart drug for enhancing efficacy. In addition, we will increase pipelines to treat incurable cancer diseases.

I would also like to expand our business area into the development of regenerative medicine, using iPSC (induced pluripotent stem cells). The iPSC does not have any moral or ethical issues as opposed to the use of embryonic stem cells, which is why we are considering developing this research area. Furthermore, iPSC can be applied to mass production of dendritic cell resulting in lowering of medical cost to patients.

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