Chae Ok Yun, Founder & CEO – GeneMedicine

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Founder and CEO of GeneMedicine, Dr Chae-Ok Yun, explains how the company, specialised in oncolytic virus development, has progressed since we last interviewed her two years ago, with one of its candidates getting close to phase II clinical trials and the construction of a new manufacturing facility that will enable GeneMedicine to grow its CDMO business.

GeneMedicine has grown since we interviewed you two years ago. Can you explain how the company has developed? and how the oncolytic virus pipeline is progressing?

Over the past two years, GeneMedicine has been growing rapidly and has made significant advancements in infrastructure, personnel, and technology. With respect to infrastructure, we have recently completed the construction of state-of-the-art GMP manufacturing facility. The facility will be utilized for the in-house GMP production of our pipelines as well as CDMO services for others. The number of experts and the overall workforce at GeneMedicine has steadily grown over the last two years to accelerate our clinical development process and accommodate our CDMO business in the near future.

Regarding our pipelines, we are currently manufacturing clinical grade GM101, which has already completed phase I clinical trials and demonstrated an excellent safety profile in patients to prepare for phase II clinical trials against triple negative breast cancer. Clinical development of GM103 is also progressing rapidly with clinical grade virus production and the preclinical study completed, and we are planning to submit the documents for IND approval this August. We are planning to conduct a phase I trial of GM103 with trial protocols that will be acceptable both in Korea and

United States in a basket trial format targeting five cancer types (cervical, ovarian, breast, colon, and renal cancers). This strategy will enable our pipeline to have good market expansion capability both domestically and internationally. In-depth preclinical analysis of GM102, which has been designed to maximize the therapeutic effect against desmoplastic and metastatic cancers like pancreatic cancer, is ongoing and currently being prepared for clinical grade virus production. The clinical trial of GM102 is expected to start during the third quarter of next year.

Getting close to phase two clinical trials for GM101 is a major milestone. What is the value of GM101 for the company?

The clinical experience with GM101 in the previous phase I clinical trial provided us with a broader understanding of how to manage our clinical development process for other pipelines. Its excellent safety profile as well as promising antitumour efficacy in cancer patients motivated us to further advance and accelerate our clinical development process for our pipelines. It gave us the firm belief that our product could improve the therapeutic outcome of numerous cancer patients.

Are you comparing your candidates to any existing therapies?

We have extensively compared the potency and safety profile of our virus pipelines with standard therapy options as well as other conventional oncolytic viruses. We have accumulated sufficient data to demonstrate that our pipelines are superior to other treatment options available in a preclinical model due to superior efficacy as well as safety.

You already had three candidates and then you added a new one with GM104. With respect to resources, why was it important to add GM104 to the pipeline?

All of our pipelines have been genetically engineered to maximize the therapeutic potential against different types of cancer, ultimately aiming to address many of the key hurdles that limit the therapeutic efficacy of conventional treatment options as well as pre-existing oncolytic viruses. The development of GM104 was essential and timely in rapidly expanding and growing the cancer immunotherapy market. Currently, commercialized cancer immunotherapeutics, like chimeric antigen receptor (CAR)-T cells and immune checkpoint inhibitors (ICI)s, are only beneficial in a small subset of the cancer patient demographic due to various obstacles in the clinical

environment. GM104 has been newly developed to address these unmet needs in patients with immunologically ‘cold’ tumours that fail to respond to standard immunotherapy options. GM104 can simultaneously boost antitumor immune response, attenuate immunosuppression in the tumour milieu, and remove the physical barriers to maximize immune cell infiltration and activation in the tumour tissues. These abilities enable GM104 to exert potent antitumour immune response in immunologically cold tumours as monotherapy and it has shown synergistic antitumour effect with a wide-array of standard immunotherapeutics. These attributes of GM104 will be important in a market where global pharmaceutical companies are actively seeking partnership or acquisition of oncolytic virus pipelines to use in combination therapy with their immunotherapeutics.

Can you explain the platform technology you are using for R&D?

The systemic delivery of oncolytic viruses have been largely inefficacious in a clinical environment and one of the major drawbacks against maximizing the therapeutic potential of oncolytic viruses against metastatic cancers. Our systemic delivery platform technology for oncolytic viruses can be utilized for many different virus types and cancer targets. The system has been developed to easily accommodate different tumour targeting moieties and utilizes complexation approaches that are applicable to wide range of viruses. Our technology can attenuate off-target accumulation in normal organs as well as enhance intratumoural accumulation of a systemically administered virus. Further, the system enables the virus to effectively evade host antiviral immunity while in blood circulation. These properties of our platform technology enable efficient and safe tumour-targeted systemic delivery of oncolytic viruses.

If the platform can be commercialised, will you look to commercial partnerships?

As our technology addresses the unmet needs of most oncolytic viruses in clinical development, we foresee that there will be a lot of commercial partnership opportunities in the future. The platform technology can be utilized for systemic delivery of different types of viruses, thus it is expected to provide our company with many partnership opportunies with other oncolytic virus providers. Additionally, the platform technology is capable of removing physical barriers, like the dense extracellular matrix of tumour tissues. This property of our platform technology makes it highly synergistic when used in combination with other therapeutic modalities, like small molecule drugs, antibodies, and cell therapeutics, as we can maximise the intratumoural accumulation and dispersion of these drugs.

GeneMedicine has built a new manufacturing facility. Will it be a part of a larger Contract Development and Manufacturing Organisation (CDMO) business or mainly for the production of your own pipeline?

The construction of our GMP manufacturing facility has recently been completed. This facility will secure our company with the in-house manufacturing capacity of our pipelines for clinical trials and launch our CDMO business that specializes in process development and the production of viruses and cell therapeutics.

How much did GeneMedicine invest to build this GMP facility?

GeneMedicine received funding of USD 48 million through series A and B, and we have invested approximately USD 30 million to produce the state-of-the-art GMP production facility covering 2,856 square meters. The facility can be utilized to produce various types of gene and cell therapeutics to address the manufacturing needs of both domestic and international clients, as our leading experts and adaptable manufacturing line can accommodate any challenges that our clients may face during the clinical development of their products.

With respect to your clinical trials, are you looking to other countries beyond Korea?

Yes, we will be conducting our clinical trials in the US and Korea. We are planning to eventually expand our clinical trials to Europe and Australia.

To conclude, do you have a particular message you would like to share with PharmaBoardroom's readers?

Although there are still many limitations that the conventional oncolytic virotherapy must address for successful clinical outcomes, we have developed several innovative strategies and implemented them into our pipelines to overcome these hurdles. Our preclinical data and clinical experience with our pipelines have been highly promising, and we are eager to advance our clinical trials to later stages. We want to be a company that offers innovative solutions that address the unmet needs of patients, ultimately aiming to provide the best therapeutic outcome for these patients as the best company specializing in oncolytic virus development.

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