Kyung Suk Kim â?? CEO, Corestem

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Kyung Suk Kim, CEO of Corestem, the first company to receive approval for a stem cell therapy for Amyotrophic Lateral Sclerosis (ALS) in Korea, recounts the firmâ??s main achievements since her previous interview with PharmaBoardroom in 2018. Dr Kim unveils Corestemâ??s new strategy to prioritise the US market and offers a glimpse into its future development pipeline.

Dr Kim, since your last interview with PharmaBoardroom in 2018, what have been the main developments at Corestem?

In early 2019, we tried to get reimbursement for NEURONATA-RÂ® under the Korean national health insurance system (NHIS). We tried to negotiate at the production cost level to benefit patients as much as possible but were not covered by insurance. This outcome led to the realization that achieving reimbursement for NEURONATA-RÂ® in Korea was unlikely. Following subsequent negotiations with the Health Insurance Review & Assessment Service (HIRA), we changed our strategy, instead prioritising the global market.

In order to enter the global market, the North American market was essential, and the level of data we had in the United States was really important. Therefore, we met the US Food and Drug Administration (FDA) in September 2019 for a preliminary Investigational New Drug (IND) meeting, briefly discussing the clinical design and protocol. Subsequently, we made our IND application for Phase III clinical trials. We have since received several deficiencies from the US FDA and are in the process of responding. We remain confident that we can resolve these issues and finally receive our

IND approval.

On our journey to develop NEURONATAÂ®, we have reached a number of key milestones. In 2014, NEURONATA-RÂ® became the first commercially licensed stem cell therapy for ALS, receiving conditional approval. Also, we finally received designated orphan drug status from the FDA in 2018 and from the European Medicines Agency (EMA) in 2019.

Since the conditional approval in 2014, NEURONATA-RÂ® has been treating more than 300 patients and has demonstrated its safety and efficacy by the Phase II results. In particular, the number of foreign ALS patients travelling to Korea to receive treatment is on the rise, as the worldâ??s first ALS treatment approval and the Phase II report has attracted the attention of academic side.

Tell us about NEURONATA-RÂ® and the technology behind it

NEURONATA-RÂ® is our pioneering treatment for ALS. ALS is a disease where motor nerve cells, which move the skeletal muscles of the body, deteriorate and eventually die. This gradually results in paralysis of skeletal muscles, progressing across the entire body. In the latter stages of the disease, a patient cannot swallow or breathe properly, relying on the aid of gastrostomy and a respirator. The prevalence rate is 4-6 in 100,000 per year, which has increased with an ageing population.

NEURONATA-RÂ® works as an autologous bone marrow mesenchymal stem cell therapy that acts as a neuroprotective effect and relieves progression of the disease through prevention of motor nerve cells and survival extension of motor neurons, releasing the nerveâ??s inflammatory and immune regulation function. The mechanism of NEURONATA-RÂ® on ALS is considered as an expression of anti-inflammatory factors, neuroprotective factors and immunoregulation.

Based on research using animal models, NEURONATA-RÂ® is considered to show recovery effects on the disease by inhibiting the immune response. Following Phase I and II clinical trials, the treatment was shown to delay the disease progression rate by on average 60 percent from the initial 1-4 month period.

NEURONATA-RÂ® has a shelf life of just 48 hours, making it difficult to distribute to patients outside of Korea. Given that Corestemâ??s current operations are limited in scope, how do you plan to realise your international ambitions?

Corestem is starting from a position as a bio venture company, now becoming more innovative and forward-thinking. We plan to first enter countries which are highly active in their policy considerations of innovative treatments for patients with rare diseases, such as the US. However, it is true that considering the size of the company, it is hard to penetrate one market alone. Thus, we have been looking for partners to license-out our technology after receiving IND approval. Fortunately, some of the major players within the top 50 pharma companies have already declared an interest in collaborating. They are awaiting the outcome of our current clinical trials before finalising any licensing-out agreement.

In the future, we also have ambitions to form partnerships in Europe. We are open to collaborations with different partners in different regions, rather than a comprehensive global deal.

Since the treatment only lasts up to 48 hours after manufacturing, shipping or flying the product from Korea, as is routine with a chemical treatment, is unrealistic. Consequently, the potentials of manufacturing NEURONATA-RÂ® in accordance with current Good Manufacturing Practice (cGMP) is the most critical point in discussions with potential partners. Furthermore, It is important to clarify, prior to any agreement, which party will control the facility and how it can be guaranteed that the facility will be able to logistically reach the whole of the USA according to GDP (Good Distribution Practice) in effect.

Aside from NEURONATA, how strong is Corestemâ??s pipeline?

NEURONATA-RÂ® is our most advanced treatment, but we have a number of others in development. Currently, we are targeting two therapeutic areas: neurological disease, and autoimmune disease. We are preparing to expand to cover other therapeutic areas in the future

Within the scope of neurological disease, we are developing a treatment for Multiple System Atrophy (Auto), which is now in Phase I clinical trials in Korea, as well as treatment for cerebellar ataxia, including Parkinsonâ??s disease, in Phase I clinical trials. We also have two other treatments at the pre-clinical stage: one for Anoxic Brain injury, and Amyotrophic Lateral Sclerosis (Allo).

Within the area of autoimmune disease, we have a treatment for Lupus undergoing Phase I clinical trials. There is currently no cure for Lupus and limited options are available to control the condition. As a result, this treatment could be of great benefit to those living with the disease

What are the main goals that you want to achieve in the next 1-2 years?

Over the course of the next year, we are expecting IND approval from the FDA and a tech transfer agreement with a partner. At that point, the make-up of Corestem will change rapidly: it will expand beyond a bio venture company.

Corestem is already listed on the stock market. Although stem cell and gene therapies are a relatively uncertain market for investors, interest has grown significantly in Korea, offering a favourable environment to attract further investment and to boost the value of the company. This interest is gradually being spread out to the world market.

As the pioneer of Korean stem cell companies, I firmly believe that other companies will follow our strategy as a route to achieving success in launching stem cell products from Korea and the widely expanded market and interest will ultimately provide treatment for all patients regardless of country, race and income.

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