Kyung Sook Kim – CEO, Corestem, South Korea

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Dr Kyung Sook Kim, CEO of Corestem, explains how her company has been pioneering the Korean stem cell industry since its foundation in 2003. She also discusses reimbursement and regulation issues that come along this expensive and complex technology and shows how stem cell therapies can be better included in healthcare systems around the world.

Mrs Kim, you have been the CEO of Corestem since 2003, and the sole representative director since 2017. How would you describe the role you have played in helping to establish Corestem's position in the market for stem cell therapies?

I started my career off as a researcher, focusing on how to apply basic research to patients. In 1998 the stem cell industry was booming in South Korea, and I had discussions with my team on how we could apply stem cell therapy, which marked the starting point of Corestem. In 2015 we reorganized the company in order to bring our first commercialized product onto the local market with the goal of also accessing the global market. Therefore, we have hired many talented people who helped us to design a global strategy. This includes getting the US FDA approval with a view to accessing the US market.

Corestem was formed in 2003, a similar time to many other stem cell companies, whose products still remain in development. How did Corestem successfully launch so quickly?

It has been a long way between founding the company in 2003 and the first approval of our stem cell product by the Korean FDA in 2014. Back then, there were no ground rules laid out by the KFDA for stem cell therapy, so Corestem has been paving the way in this regard. As our company was the first mover in the stem cell therapy sector, the path we took was adopted by the KFDA as regulatory guidelines. It required a lot of trial and error since we have reached the individual customized therapy we have today, which combines the drug and treatment measures, but being the first company in the industry was definitely an advantage.

We have received significant government support in the early stages too. As Korea is typically a follower country in the pharmaceutical industry, having a strong generics market, the government was interested in building a new innovative technology like stem cell therapy from scratch on Korean soil. Even today, we have a strong collaboration with the Korean government and doctors interested in stem cell therapy.

You are expecting that Neuronata-R will be reimbursed this year by the NHIS, nearly 4 years after approval. Within the Korean market, what have been the main stumbling blocks in negotiations, given that it is the only treatment for ALS available?

We are in continuous discussions with the government and HIRA (Health Insurance Review & Assessment Service) on the reimbursement. Like all stem cell companies, we have extremely high manufacturing costs, so our product price is naturally higher than of other pharma products. However, so far HIRA has not faced a similar case in this price range yet, so they have been very cautious. We are very collaborative on this matter, by educating HIRA on the benefits of our Neuronata-R product, while also aiming to reduce production costs to lower the price. Today, we are in the final negotiation stage and we continue pushing for reimbursement to allow the highest number of ALS patients possible to benefit from our products. As it looks now, there will be national insurance cover provided by next year. My background as a medical doctor gives me this inspiration of helping people, which is why we already have reduced the price significantly.

Last year you invested in your own manufacturing facility in Yong-In. What is the rationale of having all of these capabilities in-house?

While we are producing in this factory, we have only leased the land and the facility in Yong-In. Our rationale for this move was that the in-house factory will allow us to cut manufacturing costs, as

external stem cell production is very expensive. Our new factory permits us to better analyse our production processes and develop own GMP guidelines, which will also have economic benefits in the future. The goal is to develop our own automated processes.

Currently, there are only two approved products on the ALS market and our product is only approved in Korea at the moment. This is mainly due to the nature of how the product is manufactured, having a lifetime of 48 hours, which therefore requires production in the country of use. Receiving the US approval would hence mean for us to set up a factory with a GDP-certified production in the US. As we are still a young company, this is currently not economically feasible for us, as we have limited resources. Hence, we are also looking for licensing partners in different countries around the globe.

You have signed a joint R&D agreement with Korean pharma firm Hanlim, which also involves technology transfer. What is your partnership strategy?

Lupus, which is the product developed together with Hanlim, is currently the first clinical trial stage and within two years a second clinical trial will commence. Here, we are taking a step by step approach, as we have to identify biomarkers and indicators, but also must be available to domestic and global pharma companies, that may have an interest in in-licensing our technology. This is part of our strategy, as we believe in Corestem sustaining its identity as an R&D company, rather than mainly commercializing the products in-house.

As an industry expert, what do you think is the right way to better integrate stem cell therapy into healthcare systems around the world?

There is no one right way, but there has to be a balance between regulation and innovation. For example, we are competing with the new age of cellular therapies, but it would not be incorrect to regulate these treatments with the same rules. In our opinion, there should be more benefits for manufacturers in the rare diseases field but the Korean government’s interest in this area is limited. The US FDA, on the other hand, has changed their stance on ALS drugs, as new ways of treatment are needed.

Unfortunately, there are still some scientists think that there is no evidence for the benefit of stem cell therapy. We strongly believe we have the scientific evidence. The results of the second clinical data with this scientific evidence were selected and presented as an important clinical research

finding and received insightful commentary from reviewers in the *The New England Journal of Medicine.*

As Korea has 4 of the 7 licensed stem cell treatments globally, how do you see its potential to establish itself as a hub for stem cell treatments both in terms of development and provision for patients?

The people's interest in stem cell therapy can transform Korea into a hub for this technology, as this raises the interest of medical doctors to use it as a major treatment. The five university hospitals in Korea play also a major part in fulfilling this potential as they see stem cell therapy as the only way for treating ALS. Korea offers a great ecosystem, with highly-educated professionals and a government that has interest and gives support for this technology. The Korean FDA provides consulting to companies free of charge, to inform and educate the companies on the regulatory framework in the stem cell industry. All things considered, Korea is on a very good way to be a dominant player in the stem cell industry.

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