Jung Hyun Yun – CEO, Biosolution, South Korea

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Jung Hyun Yun lifts the lid on Biosolution's new stem cell technology that could revolutionize the treatment of cartilage-related ailments, such as osteoarthritis. He also discusses the plans for global expansion of Biosolution's cartilage cell therapeutics, CartiLife (expecting Korea FDA approval in 2019), and how their human tissue model could replace animal testing.

Mr Yun what led you to move into the biotech industry and become the CEO of Biosolution?

Indeed, I did not establish Biosolution, but joined ten years ago from my previous career as a management consultant. I decided to join the team after a meeting with BioSolution's founder, having already seen the potential within the biotech industry. Regenerative medicine is a hot topic for everyone. There are a lot of players looking to enter this market, and cell therapeutics are among the most advanced areas within regenerative medicines. Since joining, I have been in charge of the development aspects of the business.

Can you briefly introduce Biosolution and your main areas of focus?

Our company specialises in cell therapy products. 80 percent of all our employees work in R&D. We have 60 employees in total and are in the process of expanding further. Our R&D centre has delivered a variety of research achievements and products. We have been developing cell therapy products and have performed quality control in-house for over a decade. We are now attempting to commercialise our third product. We have two main categories for our business. The first is cell therapy products, and the other is the 3D human tissue model to replace toxicity testing on animals. Within cell therapeutics, our focus areas are skin and cartilage.

Our core technology is based on stem cell technology. This includes highly pure efficient cell isolation, mass scale expansion, re-enforcement of cellular functions, and differentiation, which is beyond simply mass expansion only. The first generation of cell therapeutics is purely mass expansion. We are developing the next generation. We also combine with our tissue engineering technologies to smoothen the process of cell implantation into the body.

Among the 15 cell therapeutic products approved in Korea, we have two of them and are awaiting approval for the third. The two products already in the market are for burn patients: KeraHeal and KeraHeal-Allo, receiving market approval in 2006 and 2015 respectively. We have been engaged in the whole cell therapeutic production lifecycle for more than 10 years now, achieving great success thus far.

What is your business strategy?

Biosolution also holds a number of patents from the USA, the EU, China, and Japan. Our aim is to bring the cell therapeutics to the global market, including the USA, the EU, China, and Japan. We are open to any forms of collaboration with major pharma or biotechnology companies. At the moment we have a collaboration agreement with Mundipharma, although this is limited to one product, KeraHeal-Allo.

For our human tissue model, the paradigm of toxicity testing is shifting to alternative testing methods. We have been engaged in human tissue modelling for over ten years now. There is now a ban in France for animal testing for cosmetic ingredients, and the global demand for an alternative to animal testing is increasing.

Biosolution's models have been constantly evaluated by third parties; we have submitted our cornea model to OECD test guidelines, the official test models and methods globally. We are expecting to receive registration approval for one of our models soon and are applying for approval with our skin model this year.

For the cartilage cell therapeutics, CartiLife, we are about to begin a clinical trial in the US soon, with a view to entering the global market. Consequently, we would like to explore more partnerships in this filed to achieve the goal.

What are the next steps for Biosolution?

Our next step is to introduce a new product to the market, CartiLife, which treats cartilage issues. The application was submitted to the KFDA last year and I am expecting market authorisation to be received within the next few months. As the clinical trial results were significant and promising, we remain very confident that approval will be granted.

The population is ageing, so the incidence of cartilage and knee problems will only increase in the future. Given that our technology is well suited to address problems related to ageing, such as arthritis, we decided to focus on the knee joint. One of the distinguishing features is that CartiLife regenerates the cartilage with the same distinct features as your own cartilage and is the world's first scaffold-free tissue-engineered artificial cartilage. This will enable elderly patients with osteoarthritis to receive the treatment.

Stem cells and new innovative treatments will be key for Korea to capitalise on the 4th industrial revolution. What is your overall assessment of Korea's potential to lead within this area?

The cell therapy market is still in its early stages, especially when compared to chemical drugs.

There is a strong potential for the market and a high level of demand amongst both patients and medical professionals. Korea has a lot of talented human resources in this industry. The government has begun trying to provide its support by deregulating. Nonetheless, there is still a way to go, namely because many of the regulations and guidelines are designed for chemical-based pharmaceuticals, so must be tailored to meet the specifications of the biological products. Overall, I would define it as a working process. This problem limited to Korea, adapting regulations to biological products is a global issue.

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