David Kim – CEO, Cure Therapeutics & CureCell, South Korea

Gene and cell therapies can completely cure diseases. They can reverse the progression of severe conditions and return patients to a healthy state

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Cure Therapeutics is a startup developing gene and cell therapies in Korea. Its founder David Kim explains where his passion for regenerative therapies stems from, breaks down the main hurdles standing in the way of success and describes how his company's business model focused on flexibility and development speed through open innovation is especially well-equipped to jump over them.

Before founding Cure Therapeutics, you founded another venture in gene and cell therapy, CureCell. What makes you so passionate about gene and cell therapies?

The purpose of traditional therapies, both small molecule chemical drugs and biologics, excluding vaccines which are preventive therapies, is not to cure the disease but to manage it by alleviating its symptoms. Conversely, gene and cell therapies can completely cure diseases. They can reverse the progression of severe conditions and return patients to a healthy state.

I had no in-depth knowledge of gene and cell therapies prior to participating as a project lead to assist the Korean government in crafting the National Technology Roadmap for gene and cell therapies in 2012. That is when I realized the power of these advanced therapies and the need to make them available to patients.

One of my friends introduced me to a company called Orgenesis that was seeking out Asian partners. I tried to assist them but could not find the right partner in Korea because most Korean biotech companies are still too conservative and do not see the value in disruptive innovation. In the end, I decided to create my own company, CureCell, to bring Orgenesis' novel therapeutic technology – dedicated to converting a patient's own cells into functioning insulin-producing cells as a treatment for diabetes – to the Korean market. In my opinion, diabetes is like a slow cancer that will eventually lead to death. Existing therapies cannot reverse the process.

Orgenesis and CureCell entered into a joint-venture agreement to form a CDMO business dedicated to further improving their technology, proving its superior efficacy to conventional treatments in clinical trials and then receiving approval from authorities. CureCell has since been acquired by US-based MaSTerShell, a global CDMO specialized in cell and gene therapies with two other subsidiaries, one in Belgium and Atvio Biotech in Israel. We are now ready to enter clinics. In order to speed up market access, we are targeting a specific patient population so that authorities will grant our treatment orphan drug designation. Following this approach, I believe that we can launch the technology in the next three years, gaining a first-mover advantage. After that, we will seek to expand the treatment to other indications.

We see that two years after founding Cure Therapeutics, your pipeline already includes three candidates for the treatment of cancer, diabetes and liver disease. How did you achieve this?

Two of our candidates are licensed-in from companies and institutes developing gene and cell therapies. Our diabetes treatment is licensed from Orgenesis while our IO therapy for pancreatic cancer based on NK cell homing technology is licensed-in from the Korea Research Institute of Bioscience & Biotechnology. We also have an in-house project, a hepacell therapy for inherited metabolic liver disease. We leverage our understanding of the scientific, technical and regulatory hurdles to develop these therapies and successfully bring them to market following a decentralized open innovation model. We focus on crafting the technology development roadmap, while outsourcing the rest.

Following this business model allows us to remain flexible by not having to invest in internal capabilities. It is inspired from Intercept Pharmaceutical which only had less than 20 employees when it went public on the NASDAQ by focusing on brain power instead of investing in facilities. At this moment, Cure Therapeutics only has seven.

One of the main challenges to make regenerative medicines available is the high manufacturing costs. What is your strategy to address this issue?

The main hurdles in cell therapy are manufacturability and manufacturing costs. Novartis CAR-T therapy is priced at USD 375,000 because the manufacturing process is labor intensive. In order to reduce costs, manufacturing processes need to be automated.

Scaling up is one approach companies are taking. However, there is a critical limitation to scaling up: adequation between supply and demand. The market for cell therapies is highly uncertain. As cell therapies can actually cure patients, the business model is entirely different from traditional pharmaceutical treatments. However, as patients do not require repeat treatments, market demand can only come from new patients. As a result, flexibility of the manufacturing process is key.

We also need two different kinds of manufacturing platforms: one for autologous and the other allogeneic cell therapies. Whereas allogeneic therapies are manufactured in large batches from unrelated donor tissue, autologous therapies are manufactured as a single lot from the patient being treated. As a result, autologous therapies require a point-of-care platform.

Cure Therapeutics, together with Orgenesis, has the long-term ambition to create such a platform. At the moment, the medical society and healthcare authorities are not ready to build this ecosystem for this kind of therapies. It is an incredible challenge. The reason we need this ecosystem is because some patients do not respond to allogeneic cell therapy. What we are trying to do is combine Big Data and bioscience to predict compatibility. This requires medical data standardization and a platform for biotech companies to access and use this data. Cure Therapeutics has formed alliances with Korean and global medical centers to make this happen.

What does Korea have to offer foreign companies wishing to develop advanced therapies?

Korea has a lot to offer small and medium-sized foreign biotech companies involved in gene and cell therapies and I am heavily involved in promoting our competitive advantages. First of all, in Korea, clinical development costs are 40 percent lower compared to Western countries, with the exception of Eastern Europe. The reason is that Korea is a small country and half of the population lives in the Seoul Metropolitan area. This extremely high population density reduces travel costs

significantly. Eastern Europe also enjoys this cost advantage. However, Korea also boasts a highly educated medical community with the required clinical and regulatory expertise, especially in early-stage clinical trials. Thus, they can help companies design early-stage clinical development programs to produce results faster and save costs. Moreover, healthcare provision is dominated by large, high-volume hospitals in Seoul with more than 300 beds. Asan Medical Center, one of the big five hospitals in Seoul, sees about 3 million patients annually. As a result, these hospitals can easily recruit patients for clinical trials. Finally, Korea is increasingly becoming a diverse country with populations from Western Europe, Central and South East Asia, and even Africa, making it easier to perform multi-ethnic clinical trials.

Apart from clinical trials, another advantage of Korea stems from government incentives for drug development. For example, the government provides non-diluting financing to highly innovative startup companies. Moreover, regulatory processes for clinical and market approval have been simplified, and Korean regulators have built up a lot of experience and competency. Nonetheless, more needs to be done in that area. Compared to regulatory bodies in the US and Europe, Korean regulators are less prone to interact with drug developers and learn from them. Instead, they always adopt a top-down approach.

One aspect of Korea’s ecosystem that is disadvantageous is the lack of public awareness and misinformed beliefs regarding drug development and clinical trials. There needs to be more education to make people understand the risks and benefits of clinical trials. Without the public’s support, we cannot develop the next-generation therapies to cure patients. Unfortunately, many NGOs have a negative view of drug development and are spreading their beliefs to the larger society. The industry needs to engage in open discussion with the government and patient groups to restore the balance.

In Korea, how do you assess the support of the government towards regenerative medicines?

I think the KFDA is supportive of regenerative medicines and has the experience to accurately assess them. They built up the knowledge by working with the EMA and the US FDA. However, reimbursement remains an issue. Even though the Japanese government reimbursed Novartis’s CAR-T treatment, I do not think the Korean authorities will reimburse such an expensive technology until they can run a cost-benefit analysis. At the moment, it is impossible for companies developing cell and gene therapies to provide sufficient health economic data as the number of patients in

clinical trials is too small. However, the NHIS provides a unique way to negotiate reimbursement through risk-sharing agreements. Under this agreement, expensive advanced therapies can claim national reimbursement but must reimburse the government if claimed efficacy is not realized. Until now, no company has taken this route yet.

We will also work with private insurance companies that see the benefit of these therapies to reduce their long-term costs. In Korea, 78 percent of the population subscribes to at least one private health insurance plan. About 70 percent are covered by cancer health insurance.

Moving outside of Korea, how do you plan to market these therapies in international markets?

In order to succeed abroad, Cure Therapeutics needs to establish a physical presence in key markets. We plan to open European and US operations this year. European countries offer many incentives for hi-tech companies, not only in terms of tax exemptions, but also grants such as the EU-funded Eurostars grant and local grants. I have already submitted applications to European bodies and received preliminary approval. In the US, state governments also provide grants to attract innovative companies which are easier to receive than national grants.

Meanwhile, Korean operations will also develop the Japanese and Chinese markets. Interestingly, there are 61 cities with more than a million inhabitants located within three hours from Seoul by plane. Among those, 11 cities count more than 10 million people. Moreover, this territory accounts for 28 percent of global GDP. In China, market access has become easier now that the Chinese FDA accepts foreign clinical data for registration applications. In the case of Japan, the NMPA has a uniquely advantageous cell and gene therapy regulation.

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