So Ra Park – Chair & Founder, Regenerative Medicine Acceleration Foundation

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Chair & Founder, Regenerative Medicine Acceleration Foundation (RMAF), So Ra Park MD, PhD, comments on the regenerative medicine ecosystem in Korea, the country's new legislative approach to the field, and the Korean market's strong potential for growth in Asia.*

Dr. Park, can you tell us about the Regenerative Medicine Acceleration Foundation (RMAF)?

Our foundation is a non-profit and operational organisation for the regenerative medicine industry ecosystem in Korea. Because a new act on advanced regenerative medicine was put in place in Korea last August, the need has arisen for efficient and systemic promotion of the regenerative medicine industry, improving reliability and safety through the creation of a partnership between the public and private sectors. Our foundation was established to respond to these needs and is based on the vision of building an open innovation platform for regenerative medicine and securing global leadership. The Foundation's mission is to promote public health by creating innovation in the regenerative medicine industry.

Countries and governments view regenerative medicine from different ethical, regulatory, and medical standpoints. What is the Korean approach to this innovative field and how has the new legislation changed this?

Under the new legislation, clinical research is governed by the Ministry of Health & Welfare whereas commercialization is governed by the Korean FDA, the Food and Drug Ministry (MFDS). Hospitals and clinicians that want to conduct clinical research must be certified as regenerative medicine institutions in advance. Sterile processing facilities that provide therapies for clinical research also need advance certification from the MFDS. Only certified regenerative medicine institutions can submit clinical research plans and a review committee then decides on their approval. High risk therapies need additional approval from the MFDS, and a safety management institution will also perform safety monitoring and plan long-term follow up on clinical research. For commercial development, most of the process is similar to the drug approval process. The difference is companies need initial certification as a management business for human cells etc. MFDS has adopted a tailored priority review process and a conditional approval scheme.

In other countries, many of these therapies are not viewed by regulators as first line therapies but as treatments to be used as a later stage, because there is still not enough data to prove efficacy. Is this the case in Korea?

In Korea we understand that we still need long-term follow up data. In clinical research all data is collected by the government, therefore the government can analyse all the clinical research data. The MFDS is also putting in place a new system for collecting data from clinical trials and long-term follow-up.

Which areas/applications of regenerative medicines are being prioritised in Korea today?

In Korea there are no priorities in the field of regenerative medicine with respect to therapeutics because we think all technologies are important for patients. However, what is perhaps a priority in the new regenerative medicine act is providing preferential support for clinical research and clinical development for serious conditions and rare diseases for which we do not currently have treatments. The government is making a large R&D investment in basic regenerative medicine research and development and in facilitating clinical research and the early phase commercial clinical trials.

The Korean government also considers innovation in manufacturing technology as crucial to bringing down costs. To this end, the Ministry of Trade, Industry and Energy; the Ministry of Health and Welfare and the MFDS are preparing a new national R&D fund for manufacturing technology innovation. In Korea, the CGT sector is growing, and a lot of investment has been concentrated there since last year with CGT biotechnology companies landing large export contracts. Recently, large domestic companies like Samsung, LG and SK Bioscience have also decided to invest in this area.

Does your institution provide any funding?

We support clinical research, and our foundation has designated a clinical research fund. After

approval from the national committee, researchers can apply for our grants. However, our foundation does not support research directly. We are focused on creating the roadmap for the regenerative medicine ecosystem in Korea, which is changing rapidly, just as it is in other countries.

Investment in regenerative medicine has increased globally over the last few years, but the number of regulatory fillings (FDA, EMA…) have not. What about in Korea?

The first approval of a regenerative medicine product in Korea was in 2002. Since then, a total of 15 cell and gene therapies, including immunotherapies and stem cell therapies have received approval and entered the market. This means the demand for new treatments is very high and that there is favourable support from the regulatory authorities.

The new regenerative medicine act is a law enabling clinical research supported by a national fund that facilitates product development. This act is under discussion on a public-private partnership forum. Some of the issues being discussed are patient accessibility, creating a connection between clinical research data and clinical trial data and options for expanding treatment coverage by linking public and private insurance. These are the efforts currently underway in Korea that will contribute to making our regenerative medicine ecosystem better in the future.

Korea is not an enormous healthcare market, making the globalisation of Korean advanced therapies perhaps the country's main selling point internationally. What are your thoughts on the internationalisation of Korean researched therapies?

Korea is a small market, but it has strong potential for growth in Asia. Korea is well placed to develop that market because of its geographical location at the centre of Asia. In Korea, there are more than 60 cities with a cumulative population of over 1 billion that can be reached by air within three and a half hours. In addition to geographical attractiveness, Korea excels at R&D and boasts first class medical centres for clinical trials. Therefore, I think Korea is a very good offshore market particularly because the Asian market is growing rapidly, and we are focused on Asia.

Do you have a final message you would you like to share with PharmaBoardroom's readers?

I would like to mention some of our recent efforts. For example, we organized an advanced regenerative medicine private-public partnership to gather opinions from domestic stakeholders and to promote public opinion. These stakeholders include the unit for advanced regenerative medicine, government departments and related organisations, the patients' association, civic groups and consumer associations, the industry association, and the academic association. Our foundation is moderating a series of online and offline forums in conjunction with the Ministry of Health and Welfare where guest speakers from abroad deliver speeches on the status of patient accessibility to regenerative medicine in each of their countries, covering both research and products. Taking these cases into account, the committee members communicate to create policies applicable to the Korean healthcare environment, which is very important for the regenerative medicine ecosystem.

I would like to wrap up my interview by saying that Korea is the best spot globally for regenerative medicine. We have a Korean regenerative medicine industry association and together we support strategic partnerships between Korea and overseas companies.

*** Biography of So Ra Park**

So Ra Park MD, PhD is the chair & founder of the Regenerative Medicine Acceleration Foundation (RMAF), Korea. RMAF is a non-profit organization which is, designated by Ministry of Health & Welfare since March 2021 engaging in various activities for accelerating technology developments and supporting policy developments in regenerative medicine field.

She has served very actively as a member of Advanced Regenerative Medicine and Advanced Biological Products Policy Committee, director general of We Support Clinical Research in Regenerative Medicine (WeRM), member of The Regulatory Reform Committee(RRC), and executive director of Osong Medical Innovation Foundation(KBIO) and so on. She also served as a president of Korean Tissue Engineering and Regenerative Society.

She is currently a professor at the Department of physiology, Medical College of Inha University and previously served as a dean of Medical College.

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