H. Samuel Muk â?? President & CEO, Korea Drug Development Fund (KDDF)

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The Korea Drug Development Fund (KDDF) is a government-funded organization created to accelerate innovation activities in the Korean life sciences sector. In this interview, Samuel Muk explains how he integrated an entrepreneurial approach into the organization and assesses the future of Korea as an R&D powerhouse.

Mr. Muk, you have spent your career working across multiple sectors including the IT industry, the finance industry, and the biotech industry. You agreed to take the role of CEO at KDDF in 2016, moving to the public sector. What was the main rationale behind this decision?

I had three motivations. First, after making a successful career in the private sector, I wanted to spend my time in a meaningful way at the service of the public and share my expertise. I have always thought that KDDF was the best and only organization to accelerate and catalyse innovation in Korea ever since I joined KDDF as an evaluation committee member when it was established. Secondly, I wanted the human network that I developed over the years to be used in the mission of helping the Korean healthcare sector to access the global industry scene. In a nutshell, I wanted to promote Korean developed products, such as metabolic disease medications, to my colleagues at Roche, Sanofi, or Merck. The third aspect was curiosity. I had lots of experience in dealing with global-scale pharmaceutical companies. However, my area of expertise was quite limited to CNS: Alzheimerâ??s, Parkinsonâ??s and neuropathic pain analgesics. I wanted to obtain an insight into other therapeutic areas, in particular oncology and metabolic diseases.

Could you introduce our readers to the organizational structure and purpose of KDDF?

The Korean Drug Development Fund was started by the government as a consortium of three health-related Korean Ministries: The Ministry of Science and ICT, the Ministry of Trade, Industry, and Energy; and the Ministry of Health and Welfare. The three ministries initially invested an equal sum of money in our fund. The stage of discovery is covered by the Science and ICT Ministry, the clinical-trial stage by the Ministry of Health, and the industrial development by the Ministry of Trade. The creation of the KDDF meant starting the collaboration between these three ministries. KDDF is one of the major forces in Korean drug R&D. We have supported more than 100 promising projects and provide them with funds and consulting support.

Drug development is an extremely demanding field in terms of investment. What are the funding schemes of KDDF?

One billion dollars may well be an insufficient sum of money for drug development. For this reason, we decided to focus on early-stage discoveries, while licensing out that product to big pharma in subsequent trial stages. As I mentioned, until now we have made discoveries and left further developments to the competence of private companies or academia.

After seven years, what role has KDDF played in the drug development in Korea?

Two years ago, when I became the President of this organization, I started changing the nature of the fund. At this moment we have five major platforms, while in the past we just had the conventional model, the innovative track, in which we would do a call for proposals to the R&D community and select the best according to its business-orientation. Subsequently, KDDF would provide consulting and funding. Now, several other programs have been added: the joint R&D track, the Bridge track, the Advancing Clinical Trial (ACT) program, the Licensing Partnering for Globalization (LPG) program, and the Global C&D program. The joint R&D track is simply a collaboration with a multinational corporation. For example, MSD and our organization jointly make an investment and provide development support by making a call for proposals and selecting two immune-oncology

projects â?? combination therapies with Keytruda. Once the project is successfully completed, the option to license the project will be offered to MSD. A joint R&D program with Servier in the field of cardiovascular disease is in progress and is expected to achieve great results. This type of collaboration is starting, and the model is evolving. KDDF support is expanding its support to joint R&D projects. Previously, there was no program akin to joint R&D; KDDF activities were limited to supporting innovative drug research and development projects in Korea. In the future, KDDF will expand collaborative research and corporate partnerships with multinational pharmaceutical companies, in addition to supporting innovative R&D project in Korea.

Another example is the Bridge track, where we provide, indeed, a bridge between the seed of early phase discoveries and the final drug. At the moment, we have seven scientists participating in the project, representing 120 years of experience in drug development overall. The results are very promising. Pharma companies show that they have a strong interest in licensing these products. On top of that, it constitutes a way to support the high-quality research of universities: Keytruda was developed in a partnership between the University of Kyoto and Texas.

Moreover, our ACT program is specifically designed for those biotech companies that are strongly interested in drug development but lack clinical trial experience. In this programme, our best projects receive consulting from Dr Deborah Chee, at the helm of KoNECT (the Korea National Enterprise for Clinical Trials), to understand the clinical trial procedures and strategies.

Outsourcing partners play a very important role in our strategy. LPG is our global licensing partner and KDDF collaborates with IPscent, a patent consultancy company in Korea, as well as Pharma Ventures, a business development consultancy company based in London, which act as our contractor to expedite the licensing process.

Finally, we have a Global C&D programme. In Korea alone, we established 900 new compounds destined to become new drugs. However, in a relatively small country, there is lack of possibility to find more. The focus now has shifted to foreign countries, with the purpose of increasing the number of candidates. For example, we partner with the LifeArc (Formerly known as MRC technology, UK), Lead Discovery Centres (Technology transfer organization Max Planck Innovation, Germany), and Fraunhofer IZI (Germany) where we assist them in translational research and in matching the resulting product with interested private parties. We used to be the fishermen looking for good candidates to come to KDDF, we often joke that we are at the farming stage now, but we will soon become hunters, adding the most promising drug candidates into the Korean companiesâ?? pipelines.

Drug development is highly competitive. Where would you like Korea to excel?

It is exactly the same question I received from the government and from Academia. The world is characterized by fierce competition right now, especially in oncology. My answer is simple â?? Korea has a strong scientific background, and academia has a strong potential in the field in terms of publication. Unfortunately, the industry does not have the same capability. I would say that we should focus on Korea-specific drugs with a global reach and new emerging modalities.

By Korea-specific drugs, I mean shifting from conventional diabetic cures and focusing on those diseases that constitute a serious health issue within the nation. A case in point is gastric cancer, the most recurrent form of cancer in the country: it might be less relevant in other countries, but still, it is subject to international attention. A further specific disease is multidrug-resistant tuberculosis, another fundamental problem in Korea in terms of occurrence relative to population. By successfully developing products in this field, we would assume leadership not only at a national level, but also at

an international level. The gastric cancer market, compared to the global for breast cancer and diabetes, is limited in scope. Nevertheless, it is still three billion dollars in size, so would provide a path to becoming number one in the world.

The second strategy will be implementing emerging modalities, such as oligo-nuclear complexes, or siRNA drugs, or even T-cell therapies. For example, Korea at this moment is relatively late for developing a CAR-T, so we might focus on CAR-NK, the CAR natural killer cells. In this field, Roche and a Korean company could effectively compete on the same level. Obviously, we currently can not with their capacity and their network in the sector they are already excelling at. New modalities also mean understanding how to cut the drug price up to one-tenth of their original price. For example, PD1 costs USD 125,.000 per year; while in Korea, we have the technologies to manufacture the same PD1 antibody at a very low cost. Consequently, the annual treatment price could be reduced to USD 12,000.

What have been the impacts of global partnerships on Koreaâ??s drug development?

The most important component of a global partnership is understanding the psychology and situation of big pharma companies. A good example is diabetes, where SGLT-2 inhibitors are the most prominent drug. At this moment, there is a global stand up for these drugs, as pharma companies around the world are conducting CV risk clinical trials, involving more than 30,000 patients. In Korea, it would be impossible, as it would cost USD one billion and Korean companies that have previously attempted failed as they did not have the capacity to operate at a global scale and make the required investment. Global pharma companies are working together for this; we need to learn the psychology behind it. Koreans would understand the underlying science, but it is necessary to know the global mentality behind a certain situation. Global collaborations are also formed with a view to learning the psychology and mentality.

As a key stakeholder in the Korean R&D ecosystem, what do you see as the next big step for Korea to be positioned as a global R&D hub?

In terms of biologic products, such as antibodies, the country should set up adequate manufacturing facilities at every stage â?? scale-ups as well as producing drugs for clinical trials stage on kilograms basis. At the moment we do not have the facilities as we heavily rely on Chinese and Swiss suppliers, Wuxi and Lonza respectively. We need â??model manufacturing shopsâ?•, the concept which originated in Zhongguancun, the Silicon Valley of China. The number one drone manufacturing company, DJI began exactly in this way, where a brilliant student brought his notebook of ideas to the model manufacturing shops and obtained a prototype the next day. Bringing this model into Korea for biologics products would accelerate drug production and trials significantly.

Last but not least, Academia should be strongly involved in drug development, while also implementing new technologies such as data management systems and AI.

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