Young-Woo Park – CEO, Y-Biologics, South Korea

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Young-Woo Park, CEO of Y-Biologics - renowned for their library with diversity of 1011 - unveils their plan to be the first in Korea to develop the PD-1 antibody as a treatment for cancer. Mr Park provides his assessment of the current biotechnology environment in South Korea, and the growing interest of the sector for venture capital investments.

Prior to your current role with Y-biologics, you worked at LG Chemical, and then at the Korean Research Institute of Bioscience and Biotechnology (KRIBB). Could you tell us more about your background, and the rationale behind your decision to move to a more niche start-up firm?

My speciality is in molecular biology. For almost 20 years, my work was based around the development of antibodies. At the time, gaining patents for antibody technology was the main emphasis, for example the phase display patent. I also worked on phase display technology during my time at KRIBB, a government-owned institution. I also spent 10-15 years cloning the expressions of the protein.

In 2001, while I was at LG, there were only a handful of antibody drugs that had gained FDA approval, perhaps two or three. However, I believed that the antibody field had great potential for fast growth. As anticipated, the antibody therapy field began growing quickly, so I used my own techniques to develop the antibody library. At LG chemicals my job was to focus solely on

molecular biology, cloning and expressing the genes. I am amongst the leaders in the field for this technology, which facilitated the creation of our high-quality antibody library with great diversity. However, I realized that there was a lack of manpower and investment for developing new drugs in the global market. I had thought about how to solve this issue for a long time, and then I decided to run my business to secure professional manpower and funds.

Antibody libraries are constructed by the genomic information coding for antibody variable domains, which can be derived from B cells of immune or naïve donors. We collected human bone marrow from donors and utilized phage display to build our own human antibody library. At that time the industry was in its infancy, so the regulations related to ethics and use of human cells were uite lax. Today this is no longer the case and regulations are very strict.

Can you provide our international audience with an overview of the operations of Y-biologics?

Our company is focused on the discovery and development of antibody therapeutics in various modalities including bispecific antibodies and antibody-drug conjugates. We started our business by providing an antibody screening service to other companies and have built up successful track-records. After seven years we became confident on ourselves then began to discover own antibody pipelines & novel bi-specific antibody platform technologies to compete in the global market. We started as a service provider but now we have transformed into a biotech company with great potential on the basis of excellence and expertise in antibody science.

The Nobel prize for chemistry this year was awarded for phase display, which is my speciality. Y-biologics has a human antibody library with a diversity of 10^{11}. We emphasise both the quality and quantity of the antibody library. Quantity means the diversity of the library the number of distinct elements in the collection, which directly reflects the probability of finding in the library an antibody against a given antigen. Quality means the singularity of elements comprising antibody library if an antibody library consists of highly similar genes it would be hard for one to discover differentiated antibodies from the regarding antibody library.

Our anti PD-1 antibody discovered from own antibody library well illustrates the quality of our antibody library. Every time we screen an antibody, we compare it with our competitors. We screened the anti PD-1 antibody in six months, and then compared it with Opdivo, one of the two leading PD-1 antibody treatments on the market. The PD-1 antibody had previously not been screened from an antibody library; ours was the first. We found that our antibody had superior

points in early studies.

In addition to our antibody pipeline we recently developed a novel bispecific antibody platform technology. CAR-T is highly effective, with around an 80 to 90 percent overall response rate, but it is highly personalised to the patient, making it very expensive. We concentrated on cell engager technology through bi-specific antibodies. We believe this technology has possibilities to replace CAR-T with its advantages

Our platform technology is named ALICE – *antibody like cell engager*. Even though there are some similar bispecific technologies developed by global biopharmaceutical companies we think ALiCE has its competitiveness because of the simple manufacturing procedure and unique structural advantage over current bispecific antibody platform technologies.

You are the first to develop anti PD-1 antibody in Korea, which you expect to launch in 2025. Today in South Korea, around 80%of the market is dominated by only two products, Keytruda and Opdivo. Why have Korean firms been so late to the market?

In the case of anti PD-1 antibody therapies, the market is and will still be dominated by two block-buster products Opdivo and Keytruda for years to come. Korean biotech companies tend to refrain themselves from crowded market which means intensive competition. There are numerous companies developing anti PD-1 antibodies in the global market so it is hard for small biotech companies to directly compete in this market.

However, I believe that in the case of the anti PD-1 antibody, the situation is somehow different. It is not an option to consider but it is “a-must-develop-pipeline. Firstly, currently, Opdivo and Keytruda is conducting numerous combination studies and becoming standard therapy in immune-oncology. Even after patent expiration of regarding two products other companies will not be able to penetrate the market as those would be blocked by combination therapy. Thus, to develop an immuno-oncology pipeline one must have its own anti PD-1 antibody.

What is the scope for this technology being developed among local biotechnology companies?

The biopharmaceutical industry is very large in South Korea, but there are only a small number of companies with the capability of developing these candidates for antibody drugs. Thus, there are

few companies considering developing treatments like PD-1. At the moment, the first priority of most Korean biotechnology companies is to license out in an early stage, rather than develop through late-stage clinical trials.

One of our activities is to help these small companies to screen their antibody candidates. We have a diverse range of partners, as we are very famous for developing these technologies in South Korea. We are committed to assisting in developing the Korean market in whatever way we can.

Given that PD-1 therapy is very expensive, what is the government's attitude towards PD-1

While I cannot speak for the government, I hope that we will receive support after developing the PD-1 antibody. I also hope that as the allocation of funds for healthcare increases, we will be able to see financial support for rolling out PD-1 combination therapies. Since the project is still in development, PD-1 therapies are not yet an area of importance for the government in its innovation drive. We have a partnership with the Korean Drug Development Fund (KDDF), covering the ALICE technology. However, our attempt to collaborate with the KDDF on the PD-1 project was rebuffed.

In 2016 you raised USD $13 million in funds through venture capital firms like Intervest. How easy is it for companies to source the funding?

Nowadays in Korea other industries, such as vessel manufacturing and car production are in decline, losing out to Chinese competition. Therefore, biotechnology is a new focus area. Venture capitalists believe that the future technology will be biotechnology, making it the current top-ranking investment sector for venture capitalists in South Korea. It is also very relevant to our society given that we are facing an ageing population. If you have good technology, you can find the capital in Korea, as Y-biologics did. In fact, Y-biologics closed another investment a few weeks ago to raise between USD $35-36 million, depending on the exchange rate. Our company is currently unlisted, but we plan to list it on the KOSDAQ by the end of next year. The USD $35 million-dollar size makes us one of the largest private companies in Korea.

What are your key priorities for the next 3-5 years?

We have more than 20 antibody candidates we will not develop them all on our own. We are going to develop three to four pipelines into clinical trials within the next 2-3 years. One of them is PD-1, the other is LAG-3 antibody, and finally, the bispecific antibody candidates designed with ALiCE. To commercialize within a short period of time we will consider orphan disease indications and FDA breakthrough therapy. For others, we look forward to licensing out in early stages.

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