Narihiko Yoshii – President, Mitsubishi Tanabe Pharma Korea

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Narihiko

Yoshii, president of Mitsubishi Tanabe Pharma Korea unveils the value that they are bringing to Korean patients by utilising legislation regarding orphan drugs to fast track the market entry of their products. Yoshii also provides his assessment of how low drug pricing is indirectly affecting the decisions of Mitsubishi Tanabe Pharma to base clinical trials in Korea.

How did you come to lead Mitsubishi Tanabe Pharma's Korean operations?

This is my sixth year in Korea. Prior to that, I worked as a researcher in Japan for 17 years, specializing in CNS. Following this, I moved to the drug development department, working in that area for a further seven years.

During my time in the development department, I worked on a project with global companies. Mitsubishi Tanabe Pharma was not conducting much development in Korea at that time. Consequently, with my experience in both research and development, the headquarters assigned me to the Korean Office in 2013 in order to strengthen its position locally. I became the President of Mitsubishi Tanabe Pharma Korea in April 2018.

I will take advantage of my experience and work on various problems for the future growth of Mitsubishi Tanabe Pharma Korea. I have designated the following three keywords so that all of our employees can reach their goals together: Move (First / Fast / Forward), challenge to change, and reflection

Part of Mitsubishi Tanabe Pharma's medium-term management plan is to reform and become a "*company that works with a sense of speed and is the first to differentiated values*". How does Mitsubishi Tanabe Pharma Korea achieve this mission and bring value to Korean patients?

One of the first things I did here was in-license existing medications, both Mitsubishi Tanabe Pharma's and those produced by other companies. At first, the headquarters in Japan had not actively considered expansion within the Korean market, and I focused on bringing various medications to Korea by attaining licenses and approvals from the Korean government.

There is one key example of this. In the Japanese, Korean and US markets, there is a medication called *Radicut*®*/Radicava*®, used for curing ALS. There were no medications approved in the US for 20 years to treat this disease. Mitsubishi Tanabe Pharma first received approval in 2015 for this medication in Japan, and of course, the headquarters wanted to launch this medication to the US prior to other markets, immediately commencing negotiations with the FDA.

It is true that the headquarters prioritizes big markets such as the US or Europe, compared to small markets such as those of Korea or Taiwan. However, I do not agree that we must wait for approvals from those large markets if we can receive approvals at a faster pace from smaller markets like Korea and Taiwan, and thus allow patients to have access to the medications.

Consequently, I made the decision to challenge this approach and to launch the medication to the Korean market first; Mitsubishi Tanabe Pharma Korea obtained approval in Korea. We did not wait for the US government's approval even though often we went for the US market first. Mitsubishi Tanabe Pharma Korea realised that once the required documents for the government approval are in order, we could receive approval faster in Korea than in the US. This was achieved only six months after the headquarters obtained approval from the Japanese government.

In Japan, there has been a strategy of reforms to increase the speed of bringing new products to the market. How do you assess the speed of getting these new products to

the patients in Korea?

The rules related to new drug approvals tend to change frequently in Korea. Therefore, it is very important to be aware of these changes and prepare in advance. For instance, at present certain data or documents are not required when applying for approval. However, the government could easily amend legislation, asking for additional accompanying documents by as early as next Spring. Usually, we receive a notice regarding these changes in advance. In such a case, we endeavour to submit our application prior to any changes taking effect.

To achieve greater stability, we are focusing on orphan drugs. In Korea, if a medication is designated as an orphan drug, companies are not asked to submit clinical trial data with Korean subjects. Therefore, we can use data from the US, Japan or Europe, which accelerates the application and approval process. This is why we in-licence orphan drugs so that we can apply for approval with data from other countries.

Any other disease areas that you are focusing on?

For the future business model, we will have two pillars. The first pillar is cardiovascular – our existing speciality. Secondly, we are looking to expand into CNS – a new therapeutic area. We are now at the stage of collecting various products related to CNS. Korea is the most rapidly ageing society in the world. Therefore, the importance of developing products targeted to the elderly becomes crystal clear. Focusing on the CNS area is part of following this trend too.

And another aspect of your affiliate is that you have manufacturing capabilities. You export injectable products to China, to Japan, also to Germany. So perhaps you could tell us about the rationale behind having the facilities in Korea?

Among Japanese pharmaceutical companies that have Korean offices, only Mitsubishi Tanabe Pharma and Otsuka Pharma have local manufacturing facilities. Usually, Japanese pharmaceutical companies produce their products mainly in Japan. However, that involves high production costs; it is more cost effective to manufacture in Asia, including Korea.

The rationale of a global manufacturing system is for the sake of efficiency and Mitsubishi Tanabe Pharma Korea is also supportive of this movement. Mitsubishi Tanabe Pharma has manufacturing facilities in Japan, South Korea, Taiwan, Indonesia, and China. The Korean facilities are highly specialised in manufacturing injectable products, which are exported to China, Japan, and Germany. As the Korean manufacturing facilities are specialised in making injectable products, we are looking for various injectable products that we can manufacture at our facilities to continue to

build strength in the area.

Considering the manufacturing facilities and the fast time that you can bring products to the market, how important is the Korea affiliate for Mitsubishi Tanabe Pharma?

The total sales goal for 2020 that was set by the headquarters is 430 billion Yen (USD 4 billion). The sales goal within the Japan market was set at 300 billion Yen (USD 2.75 billion). The Asian market includes South Korea, Taiwan, China, Indonesia and ASEAN. The sales goal for the South Korean market is 10 billion yen (USD 93 million) in 2020, a significant contribution to the total Asian market's sales goal. This unequivocally demonstrates the importance of Mitsubishi Tanabe Pharma Korea within the company group.

What is your footprint in clinical trials in Korea and why did you choose Korea as a place to conduct clinical trials?

We have conducted clinical trials (Asian studies) in South Korea, Japan and Taiwan previously. The clinical trials conducted in Korea are relatively cost-effective. However, one issue that concerns me, indirectly related to clinical trials, is the drug pricing system in Korea: the drug prices are very low, excessively so. Given the huge investment made by the headquarters into researching and developing drugs, the pricing makes it difficult to make a profit. Moreover, the drug price in Korea affects that of Europe and the Middle East through reference pricing. For this reason, the headquarters are becoming reluctant to have a drug price for the products in Korea. This brings an ironic result that even if companies obtain clinical trial data from Korea, there is no prospect of launching them locally. If this continues, Korea will merely be used for increasing the number of enrolled patients for clinical trials.

Which areas can Mitsubishi Tanabe Pharma leverage its experience to create further growth in the next 3-5 years in Korea?

Of course, there is no doubt that the existing areas such as cardiovascular of the current pillar, will continue to grow. As I mentioned earlier, new areas such as CNS, which was the new pillar for the future development plan, will be developed by adding new products.

As you might have heard, Mitsubishi Tanabe Pharma is a company formed by having merged numerous companies in the past. Each of the companies had their partners in Korea, and they are now partners of Mitsubishi Tanabe Pharma. It is true that those Korean partner companies are invaluable for Mitsubishi Tanabe Pharma, and Mitsubishi Tanabe Pharma Korea would love to

collaborate with those who can help us achieve our goals.

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