

Je-Man Ryu - CEO, Shin Poong Pharm, South Korea



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Shin Poong is one

of the oldest pharmaceutical companies in Korea. Established after the Korean War, the company's original mission was to provide high-quality and affordable generic medicines to the Korean people. Now the company has transitioned into an innovative developer of novel first-in-class therapeutics, including a malaria treatment on the WHO's Essential Medicine List (EML). Its CEO Jei Man Ryu explains how Shin Poong made this transition, its dedication to the health of humankind, and lays out the global ambitions of the company.

Shin Poong was founded by Chairman Chang after the Korean War in order to provide affordable and high-quality medicine. South Korea is now a prosperous nation. What is your new vision for Shin Poong?

Shin Poong was founded in 1962. From the start, Chairman Chang's vision was to build a fully integrated platform capable of manufacturing a high quality of affordable generic drugs from the API to the finished product. Since then, we have moved into developing our own innovative drugs and have several new drug development projects including innovative first-in-class therapeutics such as stroke, platelet aggregation treatment. And we have also developed a novel drug compound for malaria treatment, Pyramax, which has been approved by the EMA and added to the WHO model list of essential medicine. Last May we began distributing this product to several African countries.

We have five affiliates, with business units including manufacturing facilities located in China, Sudan and Vietnam, and sales offices in the Philippines and Myanmar. Shin Poong also exports products to developed countries. Last year our revenue was USD 176 million, 10 percent of which was spent on R&D.

Shin Poong's original focus was aligned with the epidemiological trends of the time. The Korean population was suffering from parasitic infections following the Korean War. Consequently, we introduced quality generic version of antiparasitic drugs. In the 1980s, schistosomiasis became a problem. Bayer and Merck developed praziquantel, a treatment for this condition. In Korea, no patent was issued. Only the synthetic pathway was protected by the patent. As a result, we developed this drug using a novel synthetic process and were able to eradicate schistosomiasis in Korea.

However, parasitic infections such as schistosomiasis were still prevalent in Africa, South East Asia and some parts of China. Furthermore, many of these countries lack the resources to afford quality treatments. As a result, the WHO offered to donate treatments. Because Merck's synthetic process was quite complex and costly, its drug was expensive. Consequently, the WHO approached Shin Poong and we started to collaborate on eradicating schistosomiasis. This collaboration created strong relations between Shin Poong and the WHO. In 2000, the WHO launched three essential new drugs projects for HIV/AIDS, tuberculosis and malaria. The WHO asked us to join the malaria project along with Malaria Medicine Venture(MMV) supported by the Bill and Melinda Gates Foundation. After years of work, we developed two efficient new drugs against malaria, Pyramax tablets and Pyramax granules for children. These were approved by the EMA in 2012 and 2015 respectively. We then applied for approval in each African country afflicted with the disease. Pyramax was also listed in WHO's Essential Medicine List (EML) as well as listed national guidelines in each country. In 2018, we were finally able to supply our product. Last year we commenced exports of this treatment to seven African countries. This year our goal is to add a further ten countries to the list.

Malaria is one the most life-threatening diseases in the world and is very difficult to treat. What do you think will be the global impact of Shin Poong's therapy?

Before Shin Poong, other malaria treatments were already being used but faced resistance and safety issues. Moreover, some of these drugs require patients to follow a high-fat diet for better absorption. However, access to high-quality nutrition is lacking in African countries. Fortunately, our drug does not require a high-fat diet. Clinical trials have shown that our drug has proven

efficacy even to drug-resistant parasite strains while it reduces the chance of resistance development.

Another aspect of malaria is that most of the deaths caused by the disease occur in children less than five years of age. However, limited children-friendly formulation was available. Therefore, Shin Poong developed a granular formulation for children. Thus, our treatment addresses many of the unmet medical needs related to malaria.

Our mission statement as a company is to improve the health of mankind and we try to infuse this core value into our development process. Shin Poong is not a company only interested in financial dividend, but in social dividend as well. To be perfectly honest, even though our malaria drug is having a tremendous positive impact on the lives of millions of patients, the financial benefit for Shin Poong is limited. This is because the development process was long and resource-intensive, and the WHO requires an affordable price in order to help as many people as possible.

As you mentioned, Shin Poong started with generics and transitioned into a developer of innovative drugs. How did you make this transition?

At first, because we did not have enough experience in new drug discovery and development, we started by developing high quality generics. Through the development of Pyramax, we significantly enhanced our R&D capabilities. We have made successful launches of several original products, fixed-dose combinations for hypertension and hyperlipidemia, and a novel ant-adhesion barrier during the surgery. Now we have an extensive R&D pipeline of novel first-in-class drugs, especially for cerebro-cardiovascular diseases such as stroke and thrombotic diseases.

In the case of our treatment against ischemic stroke, there are very few innovative drugs available and we hope to bring one to the global market in a few years. Last year we finished a Phase IIa clinical trial that has shown promising results for addressing unmet medical needs, allowing us to advance to Phase IIb clinical trial in a large patient population that should be completed by 2020. We are currently looking for partners that can help us bring the product to the global market.

Thanks to our research efforts, we are now recognized as one of 47 most innovative companies by the Ministry of Health and Welfare of Korea.

How do you decide on which treatment areas to allocate your resources?

We are trying to develop novel and innovative first-in-class products which can overcome the clinical unmet needs. For the field where our research experience and capabilities are limited, we are trying to collaborate with academia and research institutes in order to identify new targets or mechanisms of action. We also pay close attention to the published research for potential findings in the field of cardiology that could accelerate entry into the clinic.

Won Hee-Mok, the chairman of KPBMA, recently said that the government of President Moon needs to increase its support of pharmaceutical companies. In your view, how supportive is the government towards the industry?

That is a critical issue. Up until now, the major growth drivers of the Korean economy have been the smartphone, automotive and shipbuilding sectors. However, these sectors are facing increasing competition from emerging countries. As a result, the Korean government went searching for the most promising next-generation sectors and identified the pharmaceutical and biotech industries as candidates. South Korea has a lot of bright young individuals working in that field who have already produced amazing innovations. More and more top students are pursuing medical and pharmacy studies. Moreover, the global pharmaceutical market is one of the largest with total revenues over USD 1 trillion as well as the one of the most profitable. However, the Korean pharma industry represents a mere 1.5 percent of the global market - there is a lot of room for improvement.

Nowadays, both local traditional pharma companies and new biotech ventures are challenging the existing paradigm. In my humble opinion, I think that upto 25 years a couple of South Korean companies can manage to enter the top 50. If not in that time frame, it will definitely happen at some point. I hope Shin Poong will be one of them.

Shin Poong has several affiliates in China and South East Asia, and interestingly in Sudan. Why have you decided to establish a physical presence in these countries instead of working with partners?

Shin Poong was one of the earliest to go abroad among other Korean companies, establishing its first affiliates in the 1990s in China, Vietnam and Sudan. We decided to focus on Asian markets since at the time we did not have the capacity to go to Europe or the United States. In the case of China, Shin Poong realized early the incredible potential of the market, especially for generics.

Regarding Sudan, we chose to establish a presence there since we had relations with several African countries.

Now the next step for Shin Poong is to enter the European and US markets.

Where do you want Shin Poong to be in five years?

In five years, I would like for Shin Poong to have co-development and co-marketing partnerships established with Big Pharma companies. Our goal is to have our own drugs approved by the FDA and launched in global markets. Within ten years, our ambition is to have more than two drugs approved and be available worldwide. By that time, we hope to have the necessary capabilities to develop and launch an NDA by ourselves.

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