Li Ning – CEO, Junshi Biosciences, China



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Junshi Biosciences is an innovation-driven biopharmaceutical company with a focus on discovery and innovative drugs. Dr Li Ning, CEO, discusses being the first Chinese company to successfully launch a domestically-developed PD-1 cancer drug (toripalimab) in China, their commercialization and pricing strategies and the exciting new products and milestones that we can expect from Junshi in the upcoming years.

Junshi is the first Chinese company to launch a domestically-developed PD-1 cancer drug (toripalimab) in China in February 2019. What an accomplishment! How has this drug performed over the past six months?

So far it has exceeded our expectations! We recently received Q1 data and last month, our revenues were (USD) 11 million. To put this into perspective, most products in China take between two and three years to make (USD) 14 million. Based on these Q1 results, our projection is to make between (USD) 80 and 90 million this year. This is an exceptional level of sales which we have never encountered before.

A partial reasoning for this is that PD-1 is already a well-established product category in the market place. Furthermore, we have excellent branding and were the first Chinese biotech to have been given approval to commercialize our PD-1 drug.

The China market is highly diversified and extremely competitive, therefore ethics and safety to meet these unmet medical needs is key. In China today, there are five companies that have launched PD-1 drugs, including BMS with Opdivo® and MSD (Merck & Co. in the U.S. and Canada) with Keytruda®, and two other local companies.

As one of the first Chinese biotech's to have a commercial drug, what lessons have you learned about successful commercial launches and building a commercial organization?

Commercialization was not our forte as we are a research and innovation-based company. However, the current ecosystem in China has matured in terms of accepting innovative products for commercialization. We recruited everyone for our commercial team within three months, without the use of recruiters or headhunters. Part of the reason is that over the past three decades, Big Pharma players have established affiliates in China and built large commercial operations. Moreover, around 90 percent of our commercial team either come from MNCs or have MNC experience. The talent pool for commercialization is there.

We have also implemented a system to train our salesforce in carrying out scientific promotions based on scientific data. In addition, from IMS data, we know that around 90 percent of all cancer patients in China are treated by around 500 hospitals. Therefore, from a strategic point of view, we wanted to focus on that 90 percent and 500 hospitals first. Hence, in October 2018, we set up our sales team to specifically cover those 500 hospitals.

Pricing is of significant importance for commercial success as it has a tremendous impact on the rate of market penetration, so we determined the price point for our PD-1 through both price comparison and patient surveys. For example, we compared cost differences between China and Western countries such as the U.S. In the U.S, patients rarely pay over (USD) 5000 out-of-pocket as the majority will have insurance. In China, however, patients will almost always need to pay much more than the equivalent to (USD) 5000 or CNY 35,000 out-of-pocket regardless of income level. China has over four million cancer patients but the proportion of these patients that can afford to pay over CNY 0.2 million per year for treatment is tiny.

As an indication, we can look at the sales of Humira® in China, which are negligible in comparison to worldwide sales. Currently, sales of Humira in China only equate to USD 20 million but globally sales reach (USD) 20 billion. This is disproportionate to the population of China and the main reason for this gap is affordability. Pharmacoeconomic limitations prevent patients from accessing these drugs – this is also why national reimbursement is of great importance.

Chinese doctors and patients are known to prefer branded products over 'local products'. How has your drug been received by them and what are the market opportunities for this drug globally?

Taking melanoma as an example, there are only two products approved for the indication of second-line melanoma in China: Keytruda® and our product. After looking at the clinical data, Merck chose second-line melanoma as their first indication to run clinical trials in China. We selected the same indication and even used the same PI at Beijing Cancer Hospital. We had almost identical clinical sites across the country and similar sample sizes as well (ours was actually slightly larger). Our clinical data shows that our data is numerically better in terms of response rate and survival time.

Currently, the market size for second line melanoma is 80/20, which is much larger in terms of prescription members. This clinical data has resulted in people saying our price is cheaper and the efficacy is either comparable or better.

With regard to our global strategy, we have two compounds in the U.S. in clinical studies, and one of them is already in Phase II. We also have two Phase III multinational studies including patients from Southeast Asia and we are collaborating with partners in Europe, India and the U.S. for co-development of our PD-1 candidates, amongst other areas.

Beyond IO, Junshi also looks at cardiovascular and auto-immune diseases. What do you see as most promising in your pipeline?

Our primary advantage is our innovative research team. We currently have a research centre in the U.S. and in China working on a very rich pipeline with both small and large molecules. Initially, we began with large molecules but we are now exploring potential opportunities for combination therapy with small molecules. Our main focus is on immuno-oncology, both as mono and combination therapy, as well as immunology disease, where we have recently filed for IND (investigational new drug) in China for IL-17A (interleukin 17A) which is a pro-inflammatory cytokine.

From an immuno-oncology perspective, our most promising asset is the Anti-BTLA which we believe to be the next star. We have already begun clinical trials in the U.S and will be starting them in China later this year.

With regard to non-oncology areas, the most important focus for Junshi is unmet medical needs. In China, this is cardiovascular disease and we are developing our own PCSK9 to combat this. Amgen has already been granted approval by China for their PCSK9 inhibitor, but if we can develop our own PCSK9 inhibitor with a unique formulation and at a much more competitive price, I believe that we can compete very effectively with Amgen's drug.

Is Junshi looking at strategic in-licensing or acquisitions to complement your existing portfolio of pipeline and products?

Junshi already has more than 20 collaborations with innovative companies and their own innovative products. These products may not have approval yet but these compounds theoretically will have the potential to be combined with PD-1 drugs to become the next big star cancer therapy!

It is important to note that these are collaboration deals and not commercial deals, which is advantageous for us since these projects are still in early-stage development. Collaboration and co-development deals help both parties share risks since there is no way of knowing what will ultimately be successful. Nevertheless, we believe that there is a high probability some of these compounds will become a better combination for PD-1. For example, we have an RNAi deal, multiple VGEf deals along with other combinations including cell therapy which is the next area we will be working in, collaborating with UT Health Science Centre in Houston, Texas. Furthermore, we have a deal with a company called Anwita, based out of San Diego, California. We expect to generate three or four new products through their technology platform.

Junshi is one of the handful of companies that have IPOed on HK and more impressively, you have seen your share price hold steady. As a CEO of a publicly-listed biotech on a new board, what are some pressures you have to deal with and how do you balance investor concerns with the longer-term strategic priorities for the company?

We were very lucky to have had an incredible start, which has certainly relieved a significant amount of pressure. Currently, the share price is around HKD 30, and a significant reason why Junshi is one of the few biotechs whose share price has not decreased is our employees and investors truly believe that our company has a promising future. Our long-term pipeline is critical, and investors do acknowledge and appreciate the future potential of this pipeline.

Furthermore, we have a second IPO later this year on the new 'STAR' innovation board in Shanghai.

On a more personal note, after leaving Sanofi, why did you decide to join Junshi – amongst the many other new and innovative biotechs that exist in China – and what are your priorities for the next five years?

I spent 13 years working for the U.S. FDA as a regulatory reviewer and then moved to Sanofi. After working for almost 8 years in multinational companies, I decided to move into the innovative biotech sector and Junshi's product pipeline was very attractive. If at some point in my life, I could be directly involved in creating one or two of those big life-saving products that could end up helping a greater number of people, that would be fantastic. The reason I chose Junshi was that it was the first Chinese biotech company to develop and launch a PD-1 drug. I thought the company has great potential and I believed that my experience could make a difference.

Over the next five years, we will have at least one new BLA or NDA application submitted each year. This will either be for a new indication or for a new product. This year, for instance, we are submitting our NPC (nasopharyngeal carcinoma) indication for PD-1 and we will also be submitting our Humira biosimilar BLA – these are the two major milestones we need to hit in the next year so that we can launch these products on the market as quickly as possible.

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