Rae Yuan – President, Sinovant Sciences, China

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13.12.2019

Tags: China, Sinovant, Research, Strategy

Rae Yuan, president of Sinovant Sciences, shares the company's "transformer" strategy culminating in a strong pipeline of innovative products spanning eight therapeutic areas, and their mission to serve the needs of patients in China and the world.

Rae, prior to joining Sinovant Sciences, you worked at Roche and Novartis. How have you leveraged your experience in large MNCs to lead Sinovant Sciences?

For both Roche and Novartis, I was the Head of Development in China. One of the big advantages of working in the China division of MNCs is learning how to successfully register a drug, the talents and the medical system in the country.

From Roche, I learnt how to build something from scratch. Twelve years ago, I led the establishment of Roche Pharma Development Division in China. At that time, very few MNCs focused on developing new drugs for the China market – instead, everyone was happily selling branded generics. Roche had the foresight to set up a discovery site in 2004 and then, three years later, a full-functional co-localized innovative drug development group for the China market. Similarly, Sinovant Sciences is set up to take an integrated approach to develop a drug from Phase I all the way to approval. Some companies do not have local in-house knowledge on certain functions, and instead, they need to leverage the workforce from various CROs.

From Novartis, I learnt how to empower local talent, communicate efficiently and achieve productivity. When working for a MNC in China, it is important to keep the global HQ updated on the latest China news. By doing so, we ensure that the local success aligns with the global success. This became particularly important in 2017 when China implemented many changes to its regulatory policy, which challenged us to work with agility and global-local alignment. During my time at Novartis, we achieved 25 NDA approvals in two years' time, ranking number 1 in China and setting the record for Novartis.

Sinovant Sciences was established to be a bridge between the global innovative research and patients' needs in China. In this regard, our current pipeline is based on in-licensing novel products that are generated abroad. We are backed by Roivant Sciences, a biopharmaceutical company with a very strong in-licensing machinery, to help us find the best molecules, and Citic PE, a large China PE fund. With the Chinese biotech boom, we also hope to develop local innovative molecules and be a bridge between China discovered molecules and the needed patients worldwide. This is China's last step to become an integrated member of worldwide innovation.

Essentially, we are a "transformer" organization: we pick the *right* molecule to develop in the *right* way so that it can become a drug for the *right* patients at the *right* dose. This is why we have been able to develop such a large pipeline, consisting of 13 investigational products since Sinovant Sciences began in 2018.

Sinovant Sciences strives to meet patient needs in China today and globally tomorrow. We combine our understanding of patient needs with our strong business development machinery in the USA, to scout and find cutting-edge science.

What were the main challenges you faced when bringing these molecules into China?

Development capabilities in China are, currently, the extreme bottleneck. There are a few strong development organizations in China. However, if you take into account the size and the needs of the country, such capabilities are still in short supply. China has in-licensed or self-generated many molecules, but it does not have the matching capacity to develop them. This is very worrying to me because the development capability is not something you can understand immediately: it takes time. New drug development also needs to go through a lot of trial and error, which means failures will occur before success is reached.

With a strong investment wave in biotech and the current favourable regulatory environment, there are companies in China with a similar business model to ours and sometimes, we run to the same in-licensing opportunity, which can jack up the price. Currently, there are many discovery-based companies also in-licensing molecules at the development stage, facing a high cash burn and huge talent requirements on both ends of the development value chain. Without a reliable and consistent funding source, these companies might run into a dangerous financial position.

Sinovant, on the other hand, benefits from the economies of scale. We focus on product development and commercialisation. We dedicate our time to building an integrated system to adhere to global development standards.

Sinovant Sciences spans over eight therapeutic areas: including oncology, infectious disease, urology, metabolic disease, pulmonary disease, gastroenterology, dermatology and rare diseases. Why have you made the deliberate choice to cover so many therapeutic areas at once?

I believe for a company to be successful, it needs to have a portfolio strategy. I am worried for companies that have only one molecule in their pipeline, because that single molecule carries the entire burden of the company's success. R&D is unpredictable – even if you complete Phase III, you might still fail by receiving a rejection from the regulatory authorities or at the commercial stage. Furthermore, even when your molecule reaches the market, you can still experience market withdrawn if the patients suffer from too much unexpected severe side-effects of your drug. This is why a balanced portfolio is vital.

This type of portfolio is also important from a competition point of view. For example, there are many biotechs in China focusing only on oncology. By the time Sinovant started in 2018, it was very clear that the oncology space was already very crowded and hence, we did not want to focus only on it.

Overall, we deliberately made the choice to develop a portfolio to balance the risks, opportunity and the chances of success. Equally important, all eight therapeutic areas represent large unmet medical needs in China.

Sinovant Sciences has a diverse pipeline of 13 investigational products in development. What are the most exciting candidates within your portfolio?

They are all exciting. Nonetheless, if I had to choose one today it would be Lefamulin. Lefamulin, was in-licensed from Nabriva, and it recently received US FDA approval for the treatment of community-acquired bacterial pneumonia (CABP) in adults. In the past 10 to 20 years the new antibiotics in the market all belong to a similar class with the same mechanism of action. Lefamulin, which targets a broad spectrum of bacteria, is the first antibiotic in 20 years to have a different mechanism of action.

Lefamulin exists as both an intravenous (IV) and oral formulation. This dual formulation is a great advantage in China, considering Chinese hospitals are extremely busy. It allows patients to change from IV to oral: a CABP patient in the emergency room can first receive IV Lefamulin and then, at the time of release, they can switch to oral Lefamulin to be taken at home.

The drug has proven to be safe and efficacious in two separate global Phase III trials. Lefamulin is so safe that it can be taken by patients with kidney or liver impairment. We are even thinking of developing the drug for the paediatric population.

Another drug worth mentioning is Vibegron, for the treatment of overactive bladder (OAB). This drug has been approved in Japan already. It has also been reformulated and has yielded great positive results in Phase III trials to support its registration in the West.

We are very excited about these two drugs and hope to bring them to the Chinese market, and soon the rest of our pipeline.

With the biotech boom in China these days, there is a lot of ‘hot money’ pouring into this industry. How can an innovative biopharmaceutical like Sinovant Sciences leverage this?

As a matter of fact, the ‘hot money’ has been cooling down lately. Nonetheless, because of the stage and size of our pipeline, we have received a number of good requests from potential investors. We need to evaluate which one is the best partner for us. In addition, because private money can only burn so long, we will eventually IPO. We would like to kick off more trials before initiating the IPO process.

Many Chinese biotech companies have told us about the difficulties of finding the right talent fitted for innovative drug development and commercial success in China. Is this

the case for Sinovant Sciences?

The new operating model, like the one in Sinovant Sciences, is based on bringing molecules into the clinical stage directly from overseas. This mainly requires development capabilities.

The development capability in China started late, around 12 years ago. The skills required for development are different to that of discovery and commercialization. In development, we need to understand the market, while at the same time reading and understanding science. It takes a special “breed” of talent to bridge between science and market. Finding this is a challenge in China.

What motivated you, like many other sea turtles, to return to China to start your own venture?

China is an underserved country, with regards to talent, patients and needs. Twelve years ago, from an innovative drug development perspective, China was in a nascent stage. While I was at Roche, I compared the top 10 selling drugs in China to the top 10 in the world, and it could not have been more different! I was lucky to be exposed to the global development and regulatory system in the US and Europe. I felt that I had the knowledge and passion to help advance drug development in China. With the many talents and patients we have, I believe sooner or later, China will become a strong player for innovative drug development for not only the Chinese patients but also on a global scale.

Lastly, where do you hope to see Sinovant Sciences in five years?

Sinovant Sciences will become a successful company with more than one drug delievered to the China market – making a great contribution to serve the needs of patients in China and the world!

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