Xu Ting â?? Founder, Chairman and CEO, Alphamab Oncology, China

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Dr Xu Ting, founder, chairman and CEO of Alphamab Oncology, shares his expert opinion on the recent regulatory and healthcare reforms in China, the expertise Alphamab Oncology has in protein engineering and their mission to become a highly differentiated oncology biotech company, and Alphamabâ??s dual China-US development strategy in support of their future international growth.

Dr Xu, having been in the pharmaceutical industry in both the US and China for a long time, what do you make of the ongoing healthcare reforms in China?

Amidst all the regulatory reforms that have taken place in recent years, I think two things are really critical: first, it is China joining the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This means that China, both as a country and Chinese biotech as an industry, now has the confidence to meet global standards. Now, whether we are truly ready to compete on the global stage is another question, but this shows that we have the desire to play globally. Once this door is open, it cannot be closed. We have now stepped out into the world!

The second thing is the newly implemented volume-based purchasing policy. For now, it only involves 31 different products in the so-called â??4+7â?? major cities, so, at most, this policy will only affect 20 percent of the market. But this is still a dramatic measure that indicates the governmentâ??s desire to bring cost control and order to the whole industry.

Looking at the whole industry, there are 5000 pharmaceutical manufacturers and thousands and thousands of brands on the market. If we look at market developments in the US 50 to 60 years ago and in Japan 20 to 30 years ago, this highly fragmented pharmaceutical industry in China will consolidate. Patented drugs with superior efficacy and new mechanisms will command a price premium. Once these drugs go off patent, they will lose that premium. This transition gives patients more choice and increases the affordability and accessibility of treatments. What does this mean? It means that in the future, 30 percent of healthcare spending in China will go to 80, even 90 percent of off-patent drugs that benefit the vast majority of Chinaâ??s 1.4 billion people, with the remaining 60 to 70 percent of healthcare spending going to the truly innovative, new drugs.

In the short term, this will negatively impact the whole industry in China. Profit margins will fall and this will further squeeze the already low R&D investment within the domestic pharmaceutical industry. At the same time, we are already seeing a negative reaction in the capital markets. However, these developments are necessary for the consolidation of the industry, which will allow for the truly innovative, differentiated products to emerge, like a phoenix out of ash! These reforms are paving the ground for future Chinese pharmaceutical innovation. Certainly, it will be extremely interesting to see how the Chinese pharmaceutical landscape has changed in a few years.

What is the state of Chinese pharmaceutical innovation today?

I am very optimistic. Looking at the stage of innovative drug development, I think China is still 10 to 15 years, and in some areas, even 30 years behind the USA. But we are catching up quickly. We have many of the right conditions for the development of innovative drugs, from the talent of overseas returnees, attractive remuneration and pay scales for senior management (sometimes even higher than in the US), an encouraging investment community (started five years ago) and so on. Furthermore, our strength is in engineering. We are really good at catching up and developing new generations of products.

Furthermore, biologics is actually a relatively young industry in itself, with Genentech in the US launching the first blockbuster antibody in 1997! This means there is still a lot of opportunities here. China is only 20 years behind in this field. We can catch up that twenty yearsâ?? development in three years.

As for our limitations, the medical and clinical infrastructure is still lacking. Most reagents and medical equipment still come from Western suppliers. Our clinicians are also usually too busy to focus on clinical research, and in particular, they also tend to see themselves simply as doctors. There is a need to change the mentality of physicians and start developing a clinical infrastructure. This is important because innovation is driven by unmet medical needs. We need to know what patients need in order to develop new therapies. In China, doctors and physicians are often too busy, often having to see hundreds of patients a day and sometimes spending only five minutes per patient. Without a good understanding of the real unmet medical needs in China today, it is difficult for Chinese companies to be genuinely innovative.

Coming to your company Alphamab, what is your positioning within this evolving industry?

Alphamab is a protein engineering company with ten years of experience and knowledge in this area. Our goal is to be a highly differentiated oncology biotech company. Even though the PD-1 space is so crowded at the moment, we are confident that our late-stage oncology products are very differentiated. Everyone will recognize that the products are from Alphamab! For instance, KN035, our PD-L1 candidate is a subcutaneous injectable instead of the standard IV infusion, which we expect to have a large clinical impact.

Another product is a bispecific PD-L1 CTL-4, and we have already seen huge potential for this to be superior in terms of safety and efficacy. This is the only bispecific candidate in this class globally. We also have KN026, a Her2 bispecific drug candidate, where we are only a few months behind the Canadian biotech, Zymeworks â?? and in fact, we are already catching up rapidly due to our ability to collect clinical data from the large Chinese patient population.

We plan to file for NDA for one product in Q4 2019 and launch it in the Chinese market subsequently. At the same time, our products are also in development for the US market.

What is Alphamabâ??s global commercialization strategy?

Realistically, we will establish our commercial operations in China first. For the global market, we will start by working with partners for co-development and co-promotion before moving into establishing our own commercial operations.

As a scientist, you have to be really exploratory and bold but as a businessman, you need to be cautious and avoid any major crises. At the end of the day, you need to stay in business in order to take advantage of the opportunities that come up! I think in China today, the biotech industry is still new so it has not yet seen a major failure. Therefore, people still think that the success rate can be as high as 80 percent! But looking at the global industry, the picture is not as rosy. Even in the US, in the late-1980s and early-1990s, biotech companies started off building their own commercial teams from the very beginning and then they started to run into problems or uncertainties like the failure to receive or delays in receiving FDA approval or slow patient uptake following approval. This year, for instance, the US FDA only approved 55 products out of the tens of thousands of clinical trials conducted on new compounds!

What is positive is that under the current regulatory reforms in China, the commercial or product promotion model seems likely to change into something that is more science-driven. However, it still remains to be seen how the pricing and reimbursement system will change and what the transition period will be.

Even for us, our first product for the Chinese market was co-developed with 3D Medicines (3DMed), a leading precision medicine oncology company in China. As they are combining the use of cancer diagnosis and treatment, they had good connections with hospitals and key principal investigators (PIs), which we were able to leverage.

Do you have a final message for our international audience?

Stay tuned: China will become a major biopharmaceutical innovation powerhouse in the futureâ?? my projection is five to ten years! Certainly, we will see the first truly first-in-class or best-in-class product coming from China in the next five years.

A follow-up interview with Terry Shuai, CFO

Terry, having most recently been head of Healthcare, Asia for Deutsche Bank with over 11 years of experience in investment banking in Hong Kong, out of the hundreds of biotech companies in China, what made you decide to join Alphamab as CFO?

Having evaluated many biotech companies, I can say that Alphamab is certainly one of the most innovative companies in China. Many Chinese companies are now raising money and using the capital to in-license products to build their pipeline. Alphamab is very special because Dr Xu has developed his own organic R&D engine to develop new biologic compounds with a solid track record for a decade.

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If we look at pure biotech companies in China, this is one of the longest-running companies in China with nearly ten years of operations. Yet this company has only had one round of angel financing round. The reason Dr Xu has managed to run the company for almost eight years without major PE financing was because he has been able to build a revenue-generating biologic drug development platform by developing many biosimilar compounds and out-licensing them to other Chinese companies. The company has been very prolific in the past decade and in fact, Alphamab has been the supplier of about half of Chinaâ??s biosimilars in late-stage clinical development from 2009 to 2016. We have partnered with almost all of the major domestic pharma players in China.

Dr Xu himself has a unique combination of being an industrial R&D scientist as well as having the commercial passion to deliver truly innovative drugs not just for Chinese people but people globally. We are at the cusp of a new era for oncology therapies. PD-L1 is one of the hottest topics now but it is just the first stage in biopharmaceutical development. There will be many more innovative, bispecific, even trispecific drug combinations entering the market in the next few years. We see that Big Pharma companies are investing billions of USD into this area. Dr Xu has accumulated a lot of expertise and experience in the past decade and Alphamab has quite a few very attractive drug candidates in its pipeline.

The investor sentiment is difficult to predict at the moment. It is certainly at a new low right now. For a pharma company, if their business model depends solely on China, the risk is higher in light of the evolving Chinese pricing and reimbursement policies. Just last week, another drug price cut was announced, with cuts going as steep as 95 percent! This is causing the devaluation of a lot of

biotech companies. Alphamab is one of the few companies that have enough substance to withstand this pressure. We have been able to complete our financing round because we have a robust pipeline and strong in-house R&D driven business model with the data to back ourselves up. We also have our sights set on developing our drug candidates for more developed markets like the US and Japan, which could mitigates the risk in China market.

I firmly believe that this is the right time, and Alphamab is the right company with the right leadership team to succeed.

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