John Gong – CEO, 3D Medicines, China



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11.03.2019

Tags: China, Oncology, 3D Medicines, Precision Medicine, Diagnostics

Dr John Gong, CEO of 3D Medicines, shares the company's '3D – diagnostics, data, and drug development' approach to cancer precision medicine; his philosophy of putting patient needs at the core of the company; the innovation behind their flagship product, a subcutaneous injection PD-L1 antibody that is also stable at room temperature; and his mission to commercialize this product on global markets in the next few years.

John, the Chinese healthcare landscape has seen great changes in the past few years from regulatory to market dynamics. How do you evaluate these changes?

The future of the Chinese pharmaceutical industry is bright. Firstly, the Chinese economy is growing – albeit at a slower speed this year – and remains the second-largest economy in the world. Chinese consumers have significant spending power. At the same time, as a result of the one-child policy, Chinese society is ageing. Demand for healthcare services, including pharmaceuticals, will inevitably increase. The problem of chronic diseases like cancer and cardiovascular disease is becoming more urgent compared to 30 years ago. Today, China is the world's number one country in terms of number of cancer patients – not a good 'number one' positioning to have! Every year, four million new cancer cases are diagnosed.

The Chinese government has made healthcare reforms a priority. With policies like the '4+7' hospital tendering process, the government is seeking to lower the prices of generic drugs in order

to make these drugs more affordable as well as to relieve the financial burden of universal healthcare coverage. This is ultimately good for Chinese patients, but in the short term, it presents a challenge for biotech companies, whose valuations are linked to the expected market prices of the products in their pipelines. Nevertheless, we believe the prices are and will remain reasonable because the government is aware of the need to keep the industry sustainable as well.

At the same time, the new drug review system is becoming faster and more aligned to international norms, ever since China joined ICH in 2017. For instance, foreign clinical data can now be used in the NMPA's (National Medical Products Administration, China FDA) drug review process. Recently, the NMPA approved a new global drug first in China for the first time ever! This is in stark contrast to the old days when Chinese patients often had to wait five to ten years to obtain access to the newest innovations! In the longer term, China will become a major player in the global pharma industry and that is good for both Chinese people and people globally.

Do you see the changing landscape as a challenge or an opportunity for 3D Medicines?

I would say it is both. In the shorter term, with lower valuations, biotech companies may find it more difficult to access funding. But there has already been a handful of companies completing their fundraising in 2019 with over USD 100 million in funds raised individually. In addition, the Shanghai Stock Exchange is looking to follow the Hong Kong Stock Exchange in launching a new board for pre-profit local companies, so I believe there is still funding available to biotech companies with good business plans.

The reality is that in the past few years, there has been a rush to invest in Chinese biotechs. The environment is becoming more reasonable and realistic. Good business boils down to the fundamentals. Today, China has over 3000 pharma companies. The US pharma market is much larger than China's but it has fewer companies. We do not need that many. It is time to clean house. What the Chinese people really need is high-quality companies with high-quality products.

I am very optimistic about both the Chinese pharma industry as well as about 3D Medicines. The concept behind 3D Medicines is 'patients first'. I am very inspired by Roche's business model and Roche's slogan of 'doing now what patients need next'. I believe that if we focus on meeting patient needs, we will be able to build a good and sustainable business.

Given the importance of business fundamentals as you mentioned, could you please share the business fundamentals for 3D Medicines?

At our core, we focus on cancer. Looking at the fundamentals of cancer, cancer stems from genetic mutations. To treat cancer, you must understand its cause. We use a powerful next-generation sequencing (NGS) system to extract the relevant genetic information within 24 hours. All that data is valuable information, but you need to use bioinformatics technology platform to understand and interpret it. Subsequently, you can help doctors and patients select the right medicines or help pharmaceutical companies develop new medicines.

Therefore, there are three parts to our business: diagnostics, data, and drug development – and together, they make up the '3D' in our name, '3D Medicines'! This integrated platform that we have built since 2010 is very unique. To our knowledge, globally, few companies put all these three elements together in such an integrated manner.

Ultimately, we want to do something meaningful for people. Looking at prices, the logic is, if you sell a drug for half a million USD, maybe only 1,000 patients can afford it. If you cut that by half, 10,000 patients can afford it. Cut it by another half and maybe you have one million patients on your drug! A wonder drug that no one can afford is useless. If our product can benefit a million patients, we would be very happy and proud!

Working within the precision medicine space, do you see this as an area where China can leapfrog the US in terms of technology development and innovation? After former US President Barack Obama launched the USD 1 billion Precision Medicine Initiative, the Chinese government launched its own with the promise of USD 9.4 billion to be invested in the next decade. With the funding, talent, and infrastructure, can China advance in this relatively new field?

I do not believe it is about domination. Precision medicine is for the people and it is very individualized. Our mission is to try to help every individual patient receive the right medication and healthcare – and actually, we started doing this before Obama launched the Precision Medicine Initiative! Back then, it was very difficult because no one really understood what we were doing. But we persisted because we believed in the heterogeneity in cancer and we wanted to provide them with personalized treatments. Incidentally, I spent a few years at the National Institutes of Health in the US, which was one of the first proponents of the concept of 'personalized medicine'. In China today, following the government initiative, there are now thousands of companies with a

so-called focus on ‘precision medicine’, but most of them do not have our scale or funding. Nevertheless, this is a sign that the industry is growing healthily, which is positive.

Looking at the funding, do not forget that China has over four times the population of the US so it makes sense for the Chinese government to invest more. Also, sequencing in China in general is not cheap because most of the machines and technologies are imported from US companies, like Illumina, which is the global leader in DNA sequencing technology.

I do not think we should look at this as a competition between the US and China. Both countries, and indeed, the world, have significant market needs. No one single country can meet these needs alone. Everyone should work together to serve humanity.

From a personal perspective, I grew up in China but I am a US citizen. I do not feel like a foreigner in either country. At the end of the day, we are all humans and we all deserve to be healthy.

3D Medicines is both a platform and a product company operating in the space of cancer precision medicine. How will the company continue to grow in the next few years?

Our ambition is to become a leader in cancer precision medicine. While the incidence of cancer is rising, cancer treatments are also improving. Increasingly, cancer will become a chronic condition, and in particular, coupled with early diagnosis and treatment, patients may live with cancer for five, ten, or even 20 years! We are very balanced in our strategy. I like to say we have the two ‘wings’ of growth: diagnostics and drug development.

Firstly, on the diagnostic side, this means we need to improve our portfolio of diagnostic products to provide better services for our patients, as well as to develop our own testing and analysis capabilities further. We already have two central laboratories and we will expand them as guided by market demand and patient needs. At the moment, around 400 of our 600 employees work on the diagnostic side.

Last year, we were the first company in China to launch a product to help cancer patients choose the PD-1/PD-L1 antibody treatment. We called it ‘OK Companion’ and launched it following the approvals of BMS’ Opdivo and MSD’s Keytruda in China in 2018. Although the final price of the PD-1/PD-L1 antibody treatment in China will be less than half of the US price, it still remains very expensive for Chinese people, so many patients want to know if immunotherapy would be effective for them prior to the treatment. In addition to the financial consideration, the patients also do not

want to waste the window of treatment because not all patients have enough time to try another drug if the first one does not work! I am very proud because in the cancer diagnosis space, we rank in the top three in China. This product has performed very well since its launch in 2018 and we expect to see a dramatic increase this year, especially because a number of new PD-1 products have been approved or will be approved.

And on the drug development side?

On the drug development side, in terms of oncology, we are very lucky to have entered the immuno-oncology space, which is truly revolutionary compared to the first and second generations of cancer treatment. Chemotherapy kills cells, both tumor and healthy cells, which is not very selective. Targeted therapies respond to particular mutations or alterations as identified by biomarkers. They are usually very efficacious, but the beneficial effects may only last a few months due to drug resistance, so patients have to take a second or third drug. Immunotherapy approaches stimulate or modulate the body's natural immune system to attack the tumor. The PD-1 or PD-L1 antibodies are the backbone in immunotherapy, but they are only effective in about 10-20 percent of patients in most cancers as monotherapy. Therefore, the PD-1 or PD-L1 antibody must be combined with other drugs in order for the treatment to be effective in more patients. Through our data collection and analysis, we are able to test and suggest new combinations of therapies, as well as expand the pool of patients that might benefit from such treatments.

Currently, our flagship product is KN035, a very differentiated PD-L1 antibody for most solid tumors – the first subcutaneous injection PD-L1 antibody globally! We have already initiated two pivotal trials. This is very significant because our product means that patients do not have to go to the hospital to receive an IV infusion treatment as other PD1/PDL1 antibodies. This relieves a huge burden on patients if they can receive treatment in local clinics or eventually even self-injection at home. As our product is stable at room temperature, patients can even bring it on their travels or vacations. As cancer increasingly becomes a chronic disease, this is an innovation that will improve patients' quality of life greatly! We hope to file for an New Drug Application (NDA) or Biologics License Application (BLA) next year.

We may be a small company but we have a global vision. We are not just looking at China; we are looking at global patient needs. We also understand the importance of being highly differentiated. We cannot launch a 'me too' product in the US because there is no market value— no one would be interested. But with a differentiated product like KN035, we can generate a lot of interest for

patients and doctors outside China.

In the future, we hope to look for partners in the global market for targeted therapies and immunotherapy.

On a more personal note, you have had a very interesting and diverse career both in the US and China. What is your personal vision for 3D Medicines?

I consider myself very lucky. I grew up in China, attended the best medical school in China, and then taught at the best medical college in Beijing. Subsequently, I received further education and training in the US, after which I joined the US FDA and became part of the public service to approve “good” drugs and reject “bad” drugs. Being in public service means you have to exercise your professional judgment and do the right thing.

Nevertheless, I returned to China in 2008 because I thought there were more exciting opportunities here. However, back then, the platform for innovative drug development was still absent so I decided to work in the pre-clinical side of the industry. Through my four years with JOINN Laboratories, I worked to bring the global GLP standards to China and collaborated extensively with regulatory authorities, the pharmaceutical and biotech industry and academic institutions. I used to joke with my former US FDA colleagues that if they saw dossiers from China with my name on them, they would know that the standards will meet FDA requirements!

I helped many companies submit INDs to the US FDA, but eventually, I decided to try and develop a drug by myself! I spent some time with BL Pharmaceutical and BeiGene. At BeiGene, I was the VP of Drug Development, Government Affairs and Regulatory Affairs, and I accomplished my mission by helping them take a few compounds into the clinical stage. After that, however, I decided to cofound 3D Medicines based on the principle of patient-focused cancer precision medicine with my partner, Dr Simon Shung. My mission now is to take our PD-L1 antibody, the KN035, to the Chinese and global market so we can truly become a global commercial company.

After that, I can hopefully retire! I plan to leave the company in the hands of my capable partner, who will forge ahead and lead 3D Medicines to the next level.

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