John Yu â?? CEO, CGeneTech, China

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Dr John Yu, co-founder and CEO of CGeneTech, shares the exciting story behind the companyâ??s establishment in 2010; its balanced philosophy on new drug development and the progress of their flagship Cetagliptin

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, a Dipeptidyl peptidase-4 (DPP-4) inhibitor of diabetes drug in Phase I clinical trials at the moment; the importance of their diverse pipeline and technology platforms to sustain the companyâ??s growth; and his five-year vision.

John, could you start by introducing yourself and CGeneTech to our international audience?

It was in 1986, during my studies at Peking University Department of Chemistry where I met Mr Ding Juping, the current president of CGeneTech! We are co-founders of the company. Whenever investors ask us how long the management team has worked together, I proudly tell them my partner and I have known each other for over 30 years â?? since we were teenagers! Anyway, after graduating, I worked for two years in academia in China before moving to Kansas in the US to finish my masterâ??s degree, then a PhD and finally my post-doc. During that time, I had the privilege of being supervised by Professor Ronald T. Borchardt, who was then the President of the American Association of Pharmaceutical Scientists (AAPS). I learnt many things from him, not only in the areas of research and academia but also in terms of business. We had four different sub-research groups looking at areas like target validation, medicinal chemistry, DMPK, and formulation. He would also take us to business conferences, not just academic conferences. It opened my mind to the idea that we did not have to become professors but could also enter industry.

When I finished my postdoc, I joined a small CRO where we had many Big Pharma clients including Eli Lilly and Pfizer. In 2006, I decided to establish my first company, also called CGeneTech, in the US As the name suggests, it was focused on chemical genomics and specifically, small molecule drug composites. At the same time, MSD (Merck & Co in the US and Canada) had just launched their DPP-4 inhibitor, sitagliptin, for diabetes. It was a very significant development as the first molecular target for diabetes that was also orally administered. I also realized that some of our own proprietary compounds were functionally very similar to sitagliptin, and we received a lot of interest from many companies that wanted to purchase the compounds from us. The going rate was USD 1000 per 500 milligrams!

But I decided to focus on developing my own diabetes drug instead. I was very encouraged by the 2008 article published by Abbott about their new anticancer drug, which referenced two fragments of their compound that came from my company! That really validated the work we did.

I decided to establish my biotech company in China instead of the US for several reasons. Firstly, China has the largest diabetes population in the world. Secondly, the Suzhou Industrial Park Biotech Development Co., Ltd. (BioBAY) had just been established in 2006. In 2008 and 2009, I returned to China very often to scout the best location and finally decided to establish CGeneTech in BioBAY in 2010 due to the excellent infrastructure and services there. I recruited my former classmate, who had been working in the generics industry in China, and we raised some money from investors to start our project!

Could you share more about why you chose BioBAY in Suzhou instead of Zhangjiang Hi-Tech Park in Shanghai or Zhongguancun Park in Beijing?

Indeed, I looked at many different science and technology parks. Anyone who is familiar with the US biotech ecosystem knows about Interstate Highway 95, which runs through Boston. Why is Boston a global life sciences hub? They have a concentration of biotech companies and other R&D institutions. Here in BioBAY, you have the same concentration of early-stage biotech start-ups. We

can collaborate with other biotechs very easily.

Additionally, the infrastructure is good. What is even better â?? because many other places might offer the same or similar infrastructure â?? is the quality of the services. Since its inception, BioBAY has provided excellent services to the biotech companies it hosts. For instance, in 2011, our DPP-4 inhibitor was recognized as a National Science and Technology Major Project (å?½å®¶ç§?æ??é?•å¤§ä¸?é¡¹), a very prestigious national research designation. When we received it in 2011, we only had 11 employees and no previous collaboration with industry or research institutes so it was an impressive feat. BioBAY supported us to write the grant proposal, and they also provided us with some early-stage testing platforms.

In 2010, the life sciences VC environment was not as developed as it is today. The Suzhou municipal government provided us with some angel funding, including through the Suzhou Industrial Park (SIP) Leading Talent Program. In total, we managed to raise just over USD 1 million at the beginning.

BioBAY has been providing this seamless â??VICâ?? (Venture Capital, IP and CRO) service since they were established, which is very impressive. As BioBAY has developed, the cluster effect has gotten even stronger! Today, within this small park alone, you have 69 members of Chinaâ??s Thousand Talents Plan â?? a figure higher than some provinces. That is a very high concentration of top talents.

All these explain why we do not plan to leave Suzhou. Between 2020 and 2022, we hope that we will be able to obtain some land from SIP to build our own research centre and formulations facility.

On to your flagship candidate then, your DPP-4 inhibitor diabetes drug, CGT-8012. What differentiates it from the other products on the market?

CGT-8012 (Cetagliptin phosphate), our DPP-4 compound, is in Phase I trial at the moment. Unlike oncology trials, diabetes trials emphasize safety and population more, so even for our Phase I trial, we recruited nearly 200 people, and expect to finish in H1 2019. Then we will enter Phase II/III, no later than early-2020. The data so far is already very impressive. We are already doing head-to-head trials with MSDâ??s sitagliptin because we are very confident in our compound. Today, Merckâ??s sitagliptin is the category leader globally so we need to compete head-on with them in terms of efficacy and safety, in order to conquer the market.

Most notably, for our compound, we can use a half-dose to achieve the same or even better efficacy compared to Merckâ??s sitagliptin. This means patients can stay on the drug longer, they can use less, and it will also be cheaper.

We already have plans to launch this drug in the Chinese market ourselves. We find that Big Pharma tends to undervalue domestic companies, especially for the domestic market. For the international markets, I think simply to launch a new DPP-4 drug would be difficult because the market is so mature.

However, what is also very exciting is that a French professor has published a few papers, most recently in January 2019, that DPP-4 inhibitors can be used as a monotherapy or combination therapy with antibodies for certain cancers. This is a very exciting new field and we are already collaborating with a few other biotech companies in BioBAY to do combination clinical trials. If the results are positive, we can certainly look at international markets!

You also have a few other projects in the pipeline, including a drug for multiple sclerosis (MS), as well as a novel oral disintegrating technology (ODT) platform. How do these fit in your companyâ??s strategy?

From the beginning, we wanted to focus on ageing diseases like cataracts, but also unmet medical needs in China. Our cataracts candidate, CGT-1507, is in pre-clinical studies right now and we hope to submit our first IND by end of 2019 or early 2020.

This is why we started to develop our MS drug, which is a generic version of teriflunomide. At the moment, there is only one MS drug available on the market and it is priced at USD 1,900 a month, which is very expensive. Furthermore, in May 2018, the Chinese government announced that this drug could be listed as an orphan drug, which means an accelerated regulatory approval pathway. We would not need to conduct the full clinical trials, just a bio-equivalence (BE) study, which we will do by end-2019. We anticipate launching this MS drug in 2020, and it will be our first drug on the market!

Our ODT platform is a lyophilization technology for immediate release (Lyir) tablet, which focuses on the comprehensive breakthrough of excipients, prescriptions, processes, packaging materials and equipment in flash release preparations, and is recognized as one of the best technologies in the world.

With all these projects going on, we are starting to recruit many clinical researchers. Last year, we already recruited several, and we are looking to have around 10, if not even more, by the end of this year, to manage all our clinical trials and sites, especially as our compounds enter Phase II and III.

Unlike many other Chinese biotechs, CGeneTech seems to have a very diverse focus across therapeutic areas and also technology platforms. What is the companyâ??s philosophy behind this strategy?

In Silicon Valley, they say that it is very common for entrepreneurs to sell their first son to raise their second son. But we do not want to sell our first son â?? our DPP-4 drug â?? so we said, we will sell our nephews to raise our own sons! This is why even as we are developing our DPP-4 drug, we are also working on other projects to generate revenues.

I always tell my team, the first priority is survival. If we die, there is no story! Raising money can be very difficult, so we established our own intermediates and generics business to generate revenues. This derives from the expertise of my partner, President Ding, in intermediates and generics development, as well as his extensive local network. Then we can focus on new drug development, which will ultimately drive the increase in value and growth for CGeneTech in the future.

Similarly, we are also focused on unmet medical needs. As mentioned, some of the generic drugs we have, like our MS drug, meet serious patient needs in China. Those we keep to commercialize ourselves, and in addition to serving patients, they also help to develop our track record. We must launch products on the market; otherwise doing R&D is just another story to tell people! Only when you manage to launch a drug on the market will people trust you more. That is also what motivates us.

This perfectly combines the expertise of my partner and I. This is how CGeneTech can thrive on this unique model. We do not just burn money in new drug development, we also generate revenues,

and we bring useful drugs to patients. Sometimes investors have asked me why I do not focus on first-in-class drug development. I tell them; sure, I can â?? if you give me more money! Today, the average cost of taking an innovative drug to market is USD 2.6 billion. This is exorbitant! So when I meet investors that say they only invest in first-in-class therapies, I always tease them by asking, â??oh, so you have USD 2.6 billion?â??

Finally, I think CGeneTech also has a very strong corporate culture and mission. All of us are committed to participating in the Chinese biotech boom. This is what I also tell my employees: they have the honour of witnessing and supporting a young company to grow up! We have around 40 employees right now. Every single person is very important to the company and we care for our employees just as they care for our mission.

Looking forward then, in five yearsâ?? time, what can we expect to see from CGeneTech?

Certainly by 2024, we will have several products on the market: our DPP-4 inhibitor, Cetagliptin and our MS product, and even more in the pipeline. Five years is a great milestone to work towards. By then, I expect we will have IPOed as well!

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