Pierre A Morgon – SVP International Business, CanSino Biotechnology (CanSinoBIO)

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Pierre A Morgon, SVP International Business for CanSino Biotechnology (CanSinoBIO) – a Chinese vaccine biotech developing one of the frontrunner COVID-19 vaccine candidates – shares how his extensive international career brought him to CanSinoBIO, the deeply-rooted public health orientation of the vaccines sector, the complex realities of developing and deploying vaccines effectively on a global scale, and the learnings he hopes the global community will take away from this pandemic.

Pierre, given your extensive and global career in the vaccines industry, could you share the story of how you came to work with CanSinoBIO?

CanSinoBIO Chairman, CEO and co-founder Dr Xuefeng Yu is actually a long-time colleague and friend. Our relationship goes back 20 years, when we were both working at what was then known as Pasteur Mérieux Connaught (before it became Aventis Pasteur, and then Sanofi Pasteur), and we reconnected properly around three to four years ago. When he began preparing for their IPO on the Hong Kong Stock Exchange, I became involved in the crafting of the IPO prospectus, and I was invited to become a non-executive director. After a year as a director, we agreed to evolve the position to an executive one.

In my current role as SVP for International Business, I focus on the international side of CanSinoBIO's development and growth strategy: identifying partners for our product portfolio in selected territories where we want a presence, securing license deals, and so on. For our COVID-19 vaccine candidate specifically, the focus is on scouting possible global partners for late-stage clinical development and registration.

A lot of global attention is on the new biotech boom in China but there seems to be a global perception that Chinese innovation today is still focused on 'me too' products. What has been your impression of the science and R&D in China?

When I first started to work with the China market a couple of decades ago, there was the perception that there are some lower-tier players in China cutting corners and producing low-quality products. But in the past decade or so, the Chinese authorities have been sending very strong signals that such actions will be punished. For instance, in 2011, the Chinese Pharmacopeia for Biological Products and Vaccines was revised and today, it is actually more stringent than its counterpart documents in the US and Europe! This is just one signal that China is serious about becoming a true international player and setting a new standard. Companies in the West often underestimate China's biotech and biopharma potential at their own peril. In general, if you visit the largest Chinese cities like Shanghai and Beijing, it becomes patently obvious that China is no longer an emerging country. Sure, the rural areas are much less developed but the point is that China's ability to execute and implement its policies – sometimes ruthlessly – is a force to be reckoned with.

Today, you really have the whole spectrum of innovation. There are companies focusing on improving existing, time-tested technologies – the Chinese application of the Kaizen principle of continuous improvement if you will – in terms of yields, productivity, quality and so on. However, some really innovative technology has also emerged, such as the vector-based technology using the recombinant replication-defective human adenovirus type-5 vector that CanSinoBIO used to develop our COVID-19 candidate, and which had previously yielded a commercial product in the form of our Ebola vaccine.

Indeed, as the name of our company implies, our company is not 'plain vanilla' Chinese. It was established by Chinese returnees in 2009– 'sea turtles', as they are colloquially known – who are all excellent industry professionals with robust skillsets honed over years and years of working in the US and Canada. They are bringing the knowledge as well as their creative minds and

entrepreneurial spirit.

In addition, CanSinoBIO is always on heightened alert for potential technologies that could supplement our portfolio and generate products. I think the focus of the company is not necessarily on specific products but rather the effective lifecycle management of the overall portfolio of technologies.

You have worked with a number of European biotechs. What similarities and differences have you encountered between European and Chinese biotechs in terms of ways of working, operational styles, etc.?

I would first emphasize that people working in the vaccines sector typically possess a very strong and deeply-rooted public health orientation, which is something you do not necessarily see in other areas of the pharmaceutical industry. Let’s face it, the vast majority of our customers are healthy babies. I cannot think of a more fragile end-user of a healthcare product. In that way, the vaccines industry inherently focuses on quality and public health at its core. This is why in China and in Europe and indeed, other parts of the world where I have worked, people demonstrate the same level of passion for and commitment to public health and to vaccine development. This also explains why the global vaccines community, perhaps in contrast with other industry areas, is far more closely-knit. People tend to know each other and they work together well. Especially at times like these when geopolitical debates are growing rather tense, the vaccine community represents a healthy bridge between all the pools of knowledge, know-how and commitment to delivering solutions that exist internationally. I personally take a lot of pride in working in this sector.

In terms of differences, I would start with the perception of time in Europe versus Asia. When I worked in Asia, I realized that time was conceived of in a very different way than in the West. Admittedly, at times it feels that things are moving more slowly in Asia because there is a culture of consensus, which drives a different decision-making process. But having said this, the ability of China to mobilize resources and decision-makers in an accelerated manner is unprecedented. In my opinion, many global regulators could benefit from some valuable insights in the way the Chinese regulator, the National Medical Products Administration (NMPA), has been approaching the situation, with administration working around the clock, seven days of the week. It is honestly something I have rarely seen with any regulatory agency elsewhere in the world.

CanSinoBIO's COVID-19 vaccine is the frontrunner in the global race. Could you lay out the realistic expectations for the upcoming development and deployment of a vaccine for COVID-19?

The reality of vaccines is very complex. When we say that a vaccine is ready, what do we mean? That is a huge question. For CanSinoBIO, what we will know very soon – upon the conclusion of our Phase II trials in China – is whether our vaccine is medically acceptable, i.e. safe and effective. The next question to answer would be whether we have enough clinical evidence for Chinese authorities to approve it, after which we would be able to prepare for commercialization.

Manufacturing capacity then becomes a concern. We are talking about a huge number of doses for a country like China, let alone the global population. Imagine hypothetically that the manufacturing lead time is six months. If production starts in September 2020, the first batch will only be ready in March 2021. After the bulk doses are finished, they have to be formulated, filled and finished, so capacity is needed there too, and not to mention the massive numbers of syringes and needles for the delivery of the vaccines to the end-users. The manufacturer can expand capacity through technology transfer but it is not a copy-and-paste process, the partnering companies need to have the platform technology ready, trained professionals, the right facility and equipment under GMP operations, and so on.

How many doses would we need to immunize the population, i.e. to reach 70 percent immunization coverage, which is the estimated level needed for herd immunity to effectively stem viral circulation? It will depend on the level of effectiveness of the vaccine, on the dose regimen, and on other programmatic considerations. Therefore, it is premature to comment on the number of doses that will be required.

Once the vaccine is registered, the immunization policy decisions will be made by the respective governments of each country, as is customary.

These questions are being discussed by global stakeholders but I think the media coverage of the COVID-19 pandemic has been rather polarizing. The focus has been on either the mounting death tolls and stressful accounts of oversaturated ICUs or the 'discovery' of a vaccine for the virus without acknowledgement of the reality that the vaccine development process cannot be completed overnight and that supply of sufficient quantities will take some time.

Could you comment briefly on CanSinoBIO's plans for the international development and potential commercialization of its COVID-19 vaccine candidate?

As you might know, our vaccine candidate is being developed in partnership with the Beijing Institute of Biotechnology so there will be some public sector involvement on this topic. The general objective is of course to maximize the number of people we can immunize globally. That is ultimately in the best interest of public health. At the manufacturer's level, the focus is first on securing registration in the country of origin in order to have a reference regulatory dossier. CanSinoBIO is also working on clinical development in other countries. We already have been approved by Health Canada to conduct Phase I & II trials in Canada. In addition, we are also exploring other countries l, which have a fairly intense viral circulation at the moment, for Phase III efficacy studies because we need to be able to recruit from a large enough patient population pool.

Another priority is maximizing bulk manufacturing capacity – and CanSinoBIO is already looking to build a manufacturing facility – and partnering with the right filling and finishing service providers to increase throughput. Distribution then falls to local government and authorities.

To wrap up, what lessons and insights are you hoping that the world will take away from this COVID-19 pandemic?

The immediate best-case scenario is that we find a solution that works, whether it is our vaccine or another vaccine or a combination thereof. This is in the best interest of the world's population right now because we are losing people. We need a solution quickly.

In the longer term, I hope that as an industry, we would be able to continue to work more agilely and quickly in the way we communicate with the authorities, in the way we mobilize resources, and in the way we align our priorities. The classical development timeline for vaccines is ten to 12 years. The Ebola vaccine was developed in around four years, which was already an achievement, and I anticipate that the vaccine for SARS-CoV-2 might only require about a year, which will be a feat.

This has been made possible through the deployment of technologies accelerating the product development timeline from concept to clinical trials. However, what we cannot accelerate is the clinical testing phase. We need to ensure that processes have not been accelerated at the expense of quality and safety. However, if we are able to recruit more clinical trial subjects in more geographies, we can achieve the target subject number in a shorter space of time.

Another positive benefit from the crisis could emerge if we are able to obtain proof-of-concept for novel technologies. We have an opportunity to advance science further.

The best ultimate outcome from COVID-19 would be better preparedness for the next pandemic. It is lamentable that some of the lessons of the previous H1N1 pandemic were forgotten as the world tried to cope with the COVID-19 outbreak. In this respect, political memory is shorter than the immune memory!

On a final note, I want to emphasize that the goal of a vaccine is to protect healthy people – people that are currently stressed and scared over the situation. The industry, regulators and other stakeholders are collectively responsible for delivering a credible, safe and effective solution. Any vaccine would need to be delivered with the right amount of public education and awareness campaign so that people understand the benefits. We know that anti-vaccine sentiment is a rising issue in many parts of the world, and it has been demonstrated that anti-vaccine sentiment is highly correlated with the absence of basic medical and hygiene knowledge. In order for a vaccine to really work at immunizing the general population and prevent viral spread, it is important that community education and outreach is done properly.

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