Chi Steve Chan – Chairman & CEO, Adimmune Corporation, Taiwan

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Adimmune Corporation is the only influenza vaccine manufacturer with both EU GMP and US FDA certification in Asia, as well as the only PIC/S GMP manufacturer of human vaccines in Taiwan. Chi Steve Chan briefly discusses his earlier career as a surgeon in the US and as both a politician and business leader in Taiwan, and touches on Adimmune´s growth strategies, how they acquire and train the best talent for the business, and their developing CMO offering.

You have had a very successful career both in medicine and in politics, reflecting on your diverse experiences, can you briefly introduce yourself and the company to our international readership?

I studied medicine at Yale University in the US. Subsequently, I practised as a surgeon for Pomona Valley Hospital Medical Center in California, where I eventually became the Director of the Department of Surgery. When I returned to Taiwan, I made it my mission to help change the healthcare system in the country. I have occupied several positions within the government, these positions have included the Minister of Health and the President’s advisor. Furthermore, in 1995 I helped to establish the national health insurance program in Taiwan. We are the first country that has initiated a single pipeline universal coverage which I am very proud of.

In 2000 there was a change in government, therefore, I left the ministry and moved back into hospital management. However, in 2008 I had a brief departure from the private sector, as I was asked to help with the presidential election. After this, I was approached by the previous Chairman of Adimmune, he told me how vital it was to ensure Taiwan has access to vaccines, especially because we are not a member of World Health Organization member (WHO). It was under this remit I agreed to take over as Chairman of Adimmune. When I first took over the company, companies in Taiwan could not produce vaccines from stage I. We would import the antigen from Japan and then, would carry out the formulation, filling and packaging to provide a vaccine for the public. Therefore, we began to conduct the technical transfer, and build our manufacturing facility. Furthermore, we entered into a strategic collaboration with a vaccine company called Crucell which was later acquired by Johnson &Johnson in 2011. Just after completion of our facility, H1N1 had become a global epidemic, and thankfully, we were already able to produce the vaccine for H1N1 and provide ten million doses to the Taiwanese public.

You have a vaccine for Enterovirus 71 in the pipelineHow you are planning to market this product?

First of all, our market strategy is to gain approval from the Taiwanese government, which we are expecting to receive next year as we have finished phase III clinical trials. On this basis, we are looking to conduct two clinical trials overseas, the first being in Vietnam which has already been pre-approved by the Vietnamese government. Furthermore, this product will not only be for the Vietnamese market but the whole of Southeast Asia. The second clinical trial we want to be conducted in China.

Are there any other promising candidates in your pipeline, you would like to share with us?

In addition to the Enterovirus 71, our quadrivalent has been approved in Taiwan, which is now in the process of NDA approval in China as well. There are two other important products currently in R&D, the first is for Japanese encephalitis which will begin clinical studies next year. The second is a TTA (tetanus) product, which is an area of desperate need in China, Taiwan and the rest of Southeast Asia.

In addition to offering vaccine products, you have further CMO services such as the influenza vaccine manufacturing plant. Can you tell us more about your CMO services?

In terms of CMO services, our facility was built for two purposes: The first being our people in Taiwan and second as a CMO for Crucell. As aforementioned J&J bought Crucell which at first, we assumed would be advantageous for us. However, around two years after Crucell was bought by J&J, they decided to cancel our contract, which was entirely unexpected. Especially as we were the only vaccine company in Asia that had EMA GMP approval. Therefore, we were left with a large manufacturing facility but limited market access. We knew the only way forward was to look into a new market and form new collaborations. Subsequently, we applied for a full vaccines license in China and began to look for a collaboration opportunity in filling and packaging. We have now successfully achieved both of these goals, and two years ago, we were granted approval from Beijing to sell our flu vaccine in China. Today we are the only vaccine's company that can sell in China without having a manufacturing facility in the country.

Overall it took us five years to gain China's market approval and sell our product there. Before this, we were restricted to the Taiwanese market, which is very small and not sustainable for us in the long term. However, we had a willingness to survive and not be conquered by this setback. In addition to the Chinese market, we were seeking out new opportunities for filling and packaging. Subsequently, we established a collaboration with a company called Protein Sciences which was small at the time but in the final stages of gaining approval for their recombinant protein flu vaccine. Protein Sciences was looking for a partner that could help them with the filling, packaging, and furthermore, produce a product that would gain US FDA approval. Once we provided the filling and packaging service for them, the US FDA sent an inspector to view both our facility and manufacturing process, and we were granted FDA approval. Which makes us the only facility in Asia to have both FDA and EMA approval. Furthermore, once Protein Science was granted FDA approval in the US they obtained the licensing and marketing rights for the vaccine and Sanofi Pasteur then acquired the company.

How are you ensuring that process innovation is implemented at Adimmune?

It is for this reason that we have a strong quality assurance department. We ensure the people in quality assurance are highly qualified and have the freedom and authority they require to ensure the highest possible standards. All products must go through their approval first, moreover, they have the authority to send a product back if for some reason it does not meet our standards. Both

the EMA and the US FDA conduct re-inspections every two to three years and we have been through this process three times so far, every time passing without difficulty. Furthermore, teamwork is of vital importance to us; therefore, we have both an executive and operations meeting once a week. In these meetings, we encourage all of the department chiefs to discuss any pressing issues and work out potential solutions.

What is your overall growth strategy and how do you respond to global competition, from cheaper manufacturers as well as larger multinational competition?

Our growth strategy is to become global! When I took over the company, I understood that to survive we needed to become a global competitor. Every product and process we have needs to meet international – not local – criteria, as the Taiwanese market is far too small. This is why we have branched into China, however, we cannot rely on the Chinese market alone. We are also expanding our reach into the US. Concerning global competition, the Taiwanese government already enforces an open market policy. For example, GSK, Sanofi, and Novartis all enjoy full privileges in Taiwan, therefore, from the outset, we have been competing with these companies. Furthermore, the Taiwanese government has a purchasing program in place, which is an open bidding process. Therefore, we are not given any guarantees of being chosen again year on year. Therefore, we need to be vigilant concerning our quality and pricing structure to compete.

With the introduction of 5+2 in 2017, have you seen government support for national biotech companies increase?

I have not seen this, at least for Adimmune. As I mentioned, in Taiwan we have to bid, therefore, if we do not get both the quality and price correct, there is no technical barrier to protect us. For example, Japan was able to produce 100 percent of flu vaccines on their own, through domestic producers. The Taiwanese government has a policy where they have divided the bidding into three companies. If you have the best price and best quality then you will be approved, however, a single company cannot control more than 50 percent of the market share.

Acquiring the best talent and then retaining this talent can be extremely difficult, with so much competition. What is Adimmune doing to attract the best talent, train them and incentivize them to remain for the longer term?

This is very tough! As we are the first vaccine company in Taiwan, we have no talent pool to draw from elsewhere. We need to educate and train our people from the ground up and fortunately, we have a well-educated and skilled workforce. Taiwan has an established education system, so much so that 90 percent of our population have degrees, subsequently there is also a high percentage of people postgraduate degrees as well. When these people enter the company, they do not have all of the skills from the outset, therefore, we have to train them. There is a lengthy learning curve in our company, and we invest heavily in our employees to ensure we are getting the best out of them. In turn, they are very loyal.

Over the next five years, what is your vision for Adimmune?

In five years, I would like to see that we have become an even more competitive player in Asia and have a firm international presence as well. We are open to working with any international biotech companies which are looking for a strong partner. I want international companies to see our talented and well-educated workforce, which will help them to understand that Adimmune can deliver.

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