Michael Chang – Founder and Chairman, OBI Pharma, Taiwan

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Dr Michael Chang, founder and chairman of OBI Pharma, shares the history of his company's beginnings and highlights the current progress of its innovative immune-oncology pipeline. Dr Chang goes on to comment on the condition of the Asian market while explaining his vision for OBI as a biotech role model in strategy, quality, and patient care.

Please begin by introducing yourself and OBI Pharma.

I am the founder of OBI and its parent company Optimer Pharmaceuticals. Optimer was founded in 1999 and OBI in 2002, originally as a subsidiary. While the parent company's focus was in anti-infective innovation, OBI was more focused on oncology and biologics – mostly immunotherapies. Early on as we began to receive more and more funding from Taiwan investors, diluting the shareholding of Optimer, which eventually led to a spin-off in 2012. OBI went on IPOed in 2015.

I grew up and was educated in Taiwan, receiving my BS in chemistry. I later moved to the US and received my PhD in organic chemistry from Brandeis University and conducted postdoctoral research at the Massachusetts Institute of Technology (MIT). I entered into the industry by joining MSD for ten years in the cardiovascular/inflammation area then, later on, moved to Aventis and headed its drug discovery.

I became an entrepreneur and started my own company Pharmanex, later merged with NuSkin. My second company was Optimer which was later sold to MSD. Finally, OBI was founded which was my third company.

What opportunity did you identify when establishing OBI in Taiwan?

Initially, we set up the subsidiary in Taiwan to support the country's biotech innovation and development landscape. Coming from a market with historical strength in manufacturing, CMOs, and CROs, we knew that innovation was important. We were hoping to act as a role model for Taiwan and show that despite being a small country with a small market and limited market capital, biotech is possible.

When we first started it was a challenge due to Taiwan's lack of experience, in a broad sense. Although the government has good intentions, they do not know how to lead the industry along. The weakness of Taiwan's biotech industry comes from the difficulty in translating research from academia to the industry. Furthermore, the long-term business model does not exist. Many players in Taiwan carry out the discovery, create a company and do proof of concept, then license out. In Taiwan, this is seen as a success, however, pharmaceutical companies with an established brand who are recognized in global medicine are almost nonexistent.

This continues to be a problem in Taiwan, but OBI's goal is to create products/brand from A to Z and bring them to market ourselves. We are open to finding partners in major markets like the US and Europe, but the brand is ours and we will maintain it, i.e. NDAs and DMF.

At the beginning of this year, you initiated a global phase III trial in breast cancer patients with Adagloxad Simolenin. How is the study going so far?

As a small company with limited resources, carrying global trials is challenging. We have enough funding to run the trials which cost about USD 70 million, we are also facing the challenge of attracting participants. Adagloxad Simolenin is running a triple negative trial in breast cancer and there are many players in this space in developed Countries, especially with PD-1 and PDL-1 mABs. To gather enough patients, we must register in many countries and sign on hundreds of hospitals. If all goes well, we plan to complete phase III within three years and afterwards follow the patients for an additional year.

What is the commercialization and development strategy of OBI? Is partnering with leading MNCs in the immune-oncology space ultimately a potential opportunity to explore?

We are confident that we will be able to succeed, therefore, by partnering prior to demonstrate clinical success for the sole reason of obtaining additional funding does not make sense. Coming from big pharma, I recognize that they are not as agile as OBI. For the sake of speed and efficiency, it is better to carry out the trials on our own and perhaps find a marketing partner after NDA. However, for our early pipeline products, it would be a different consideration. After an early clinical proof of concept, working with a partner in a joint venture format for development could be a better option since most of our early development candidates have multiple cancer targets. Leveraging MNCs' bandwidth and going after different targets simultaneously would expedite the development and increase the chance of success.

How has OBI recovered after the initial trials of Adagloxad Simolenin did not meet their desired outcome?

It is ironic that this trial of Adagloxad Simolenin not meeting primary endpoint was so publicized. When we first started the trial, it was an exploratory phase II where we took all metastatic breast cancer patients. We were trying to prove a clinical concept and hoping to identify which groups this compound could benefit. However, the government was very excited that we were running such an original trial (meaning first-in-class) and wanted to support us. While we were originally looking for approximately 200 patients, we increased this to 350 to allow the flexibility to designate it a pivotal trial. Globally, however, this was still a phase II trial. But in Taiwan, it was labelled as a phase III pivotal trial, which was not the original intent or design of the trial. Therefore, when the outcome did not meet the endpoint overall, it was labeled as a failure which was not necessarily the case.

Although the trial did not meet the endpoint, it was very telling and helped us with the direction to move forward with development. We learned that when injected with OBI-822, patients must be able to produce antibodies, and enough of them to result in a good clinical outcome, and they must have a high enough level of the Globo H antigen on its cancer cell. Now we design the trial to screen for Globo H score and we selected a group of triple negative and low ER positive patients as the target treatment group. We are optimistic for a successful outcome of such a trial.

More than 60 percent of the cancer pipeline therapies are under clinical evaluation. Of the total number of clinical candidates, close to 100 CAR-T therapies are in the mid to late stages of development and are anticipated to enter the market in the next five to ten years. How involved is OBI in this space?

We are working on CAR-T/CAR-NK as well, using GloboH series antibodies as guiding/homing protein. While it is a good concept there are still many challenges. A homing target is necessary to bring the T cells into/near the (solid) tumor, and that is difficult to achieve due to selectivity and other physical barriers. For now, it is mostly being used for Leukemia and blood cancers as it is easier to reach the target cells than with solid tumors. Currently, the most common method is the viral approach which takes a few weeks before the modified T cells are safe to be injected back into the patient, at which time cytokine storm risk is high. Finding the right target is crucial, which is why using Globo H is very effective in theory as it is not expressed in normal cells, giving an excellent homing ability into the tumor. We are still working on developing a non-viral method to create CAR-T and CAR-NK so that the time these cells outside of patient can be minimized. OBI is also working on non-viral methods which results in a process yields extraordinarily high purity and only takes a matter of days rather than weeks. Furthermore, we are working on natural killer (NK) therapies which may not have to be individualized – an important step in overcoming the hurdle of the treatment cost.

Immunotherapies are still very expensive treatment regimens. Given that health systems are under severe pressure to control healthcare inflation, how would you assess the potential of these novel treatments, including OBI´s immunotherapy, to not only be available and approved but actually accessible?

OBI is not aiming to make profit in Taiwan – we are focused on the global market. In Asia, it is impossible to charge high prices for drugs with a few exceptions. However, in the emerging markets, there are small populations of wealth who can afford these kinds of treatments. At OBI, we are more focused on helping patients and making innovation accessible that making high revenues. Our aim is to sell our therapies to the populations who care afford it and use the revenues to support making cell therapy available for free to patients who cannot afford it.

Part of the biopharma story is taking place in Asia in places like Hong Kong. Shanghai, Shenzhen, Seoul, and Osaka. What do you see as the impact of pan-Asian ambitions coupled with such a large population and disease scope?

Taking the cancer treatment market, for example, the market is still not very big for most of Asia, but there is a high potential. In China, only five to ten percent of the population can afford most advanced western treatments but the population is enormous. This is why China's market is coming up very quickly, however, the innovation and quality base is not strong yet. Additionally, with players like Japan and South Korea, there is a strong opportunity in the region, but the right marketing strategy is essential for success. In Western markets, we will find marketing partners in big pharma for products, while in Asia we will carry out these activities ourselves.

Putting aside ideologies and politics, China and Taiwan are neighbors that speak the same language. How can you tap into this market and take advantage of its huge resources?

We need to find a partner very early on and we have been trying since 2012. However, we have not been able to find any reliable partners thus far. Since we have the knowledge and experience ourselves, we are considering working with financial groups to create an enterprise ourselves. As many players in China do not care about IP rights or quality, this may be the best option for us. OBI's primary focus is on the patient and giving the best treatments possible.

What strategic priorities to you have for OBI in marching towards your long-term objective of becoming a world-class innovative anti-cancer drug company?

Over the next five years, we must achieve some sort of success, either the proof of clinical concept of an early stage development candidate or a drug reaching the commercialization stage. OBI has a platform with eight compounds in development and are on the right track to achieve this goal. Next, we want to build a strong team of experts who have gone through the process hands-on at OBI. Therefore, we are very focused on training our young talent to continue building in the future. Additionally, we want to stabilize ourselves financially to be on a solid foundation so that we can further develop our platform and technologies. Finally, the science behind everything is an essential key to success. We are comfortable with what we are trying to accomplish, and we want to bring this expertise to the market through our products.

OBI’s mission is not about being the biggest or the most successful company in the country. Instead, we are aiming to be a role model for Taiwanese biotech while helping as many patients as we can.

How do you successfully merge science and business while running a biotech?

You cannot force these two areas to come together. In order to have a successful business, having a business-minded leader is key. My advantage in being a scientist is that I am able to check and see if the science behind our products is right. However, more importantly, I am still a chairman/CEO with good sense of business and a proven track record.

I would like to see Taiwan brew successful companies in the future, at the same level of international big pharma. However, I do not believe we are there yet. With the right platform, funding, and team, I believe Taiwan can produce a few key players within the next ten years.

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