Today Su – CEO, Golden Biotech Co. Ltd.



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06.09.2019

Tags: Taiwan, Biotech, Botanical Drugs

Today Su, CEO of Golden Biotechnology, introduces the innovative biotech developing a revolutionary botanical drug derived from the Taiwanese fungus

Antrodia Camphorata. The company's drug, Hocena®, has already received several orphan drug designations and thus far has exhibited promising results in key indications such as pancreatic cancer, non-small cell lung cancer, and even Alzheimer's disease in animal models.

Mr. Su, you are a newcomer to Golden Biotech only joining the company in March. As an experienced business development professional, can you please introduce yourself and your journey to the company?

I am a trained scientist who has worked in the industry for over two decades. I have been through many of the major challenges in Taiwan's biotech industry. When I first joined the industry, I started in a biologic therapeutic vaccine company then later on a genomics company – two major areas which have gotten high attention from Taiwan. Realizing even the most promising biotech companies, like the two I joined, would still be in need of money throughout their life-cycle, I shifted gear to in a venture capital firm for first hand buy-side experiences about the financing dynamics in related industries. Later on, I joined a medical device company specialized in innovative low dose X-Ray for cancer treatment. Subsequently, I returned to the vaccine sector as

the Chief Strategy Officer of Adimmune and was tasked to bring their product to the European market. Most local pharmaceutical and biotech companies face a major challenge in expanding out of the domestic market. After conducting the largest clinical trail ever conducted for a Taiwanese company with over 2000 participants, the company got its ticket to access the market and I gained valuable professional experience.

Golden Biotechnology Co (GBC) is a drug development-oriented biotechnology company that was founded in 2002. With the world's leading drug screening platform, GBC is able to rapidly screen the effectiveness of components along with the help of domestic and foreign top medical scientists to create the best team of both worlds. In 2005, after stopping the screening process, our president, Alex Liu, identified the top ten strains from the platform. Miraculously, it was discovered that in human use Antrodia Camphorata, a local fungus, was much safer than traditional cancer therapies in every aspect in treating liver cancer.

Antroquinonol aka Hocena® has reached global phase II studies in two indications: pancreatic cancer and non-small cell lung cancer. Therefore, it was a good time for me to join the team because most Taiwanese and even Chinese companies only have local, not international, clinical trial data. As we already have USFDA Orphan Drug Designation (ODD) in treatment of pancreatic cancer, acute myeloid leukemia (AML), and hepatocellular carcinoma (HCC), GBC was well positioned to really focus on international expansion.

How would you describe Golden Biotech's strategy to develop the antroquinonol compound into a new-formulation botanical drug?

We are focused on targeting key indications in most major therapeutic areas. At first, many people thought Antroquinonol would only be used in treating liver conditions as the compound was traditionally used in this specific area.

GBC has been marketing this fungus as a functional food in Taiwan for over ten years. The feedback we received from consumers has been very precious to us as from it we realized Antroquinonol has the potential to treat more conditions than we previously expected.

In a normal drug development process, researchers will observe specific functions when doing tests in animal cells. However, GBC observes the efficacy of antroquinonol in humans first through the effects of the food supplement, and then we study its functions in animals. This allows us to have a higher success rate in trials as we have already established the observational data in humans

which are much more complicated than in animals. Afterwards, we investigate further to fulfill the requirements of drug regulatory bodies.

How is antroquinonol a new solution compared to traditionally developed chemical drugs?

Although we are conducting trials in different indications such as liver cancer, non-small cell lung cancer, and Alzheimer's disease, this is following an organ-centric approach which was defined in the past for the convenience of physicians. However, GBC believes that diseases and health go beyond the factor of a single organ, just like how exercising benefits not just one muscle but the entire body in different ways. Therefore, GBC's philosophy is that with one small molecule we can help treat patients from a multi-functional approach rather than targeting just one single factor as is the case with traditional chemical drugs.

When treating cancer, patients would suffer from many different side effects for which they would have to take other medicines to balance. However, GBC's treatment offers patients additional health benefits while treating their cancer. If a drug is artificially developed, it is difficult to predict how it will react in the human body, but because antroquinonol is derived from a natural source we can more easily understand how it functions. Even in our research, we have seen that the compound is safe at very high concentrations unlike toxic chemical drugs.

Golden Biotech's most recent focus has been in the indication of Alzheimer's disease in which it is collaborating for pre-clinical development with Queensland University of Technology and J&J in Australia. In a space with such a high failure rate where many big pharma players are pulling out, how do you expect to be successful?

GBC has analyzed all the failures of Alzheimer's trials over the past several years and so far, no drug has adequately addressed the disease. To be more specific, chemical approaches targeting a single disease factor showed promising results in animal models but this single pathway approach is apparently not sufficient enough to generate outcomes in human trials as promising as in animal models. Thus we believe Hocena®'s multiple, simultaneous, and synergistic actions may enable more positive outcomes.

Our drug under development, Hocena®, exhibits metabolic effects by regulating the AMPK and mTOR pathways, which control the downstream pathways of cholesterol, fatty acid synthesis, and

lipogenesis. The drug has demonstrated its ability to cross the blood-brain barrier, reduce inflammation, and improve vascular diseases and metabolic disorders. Early studies, for instance, indicated Hocena®'s ability in improving learning and memory and in reducing amyloid-beta levels and inflammation in the brains of animal models.

By entering such a wide field of therapeutic areas, there is also an added burden of conducting trials paired with a higher risk of failure. How does Golden Biotech manage this challenge?

For the long-term development process of diseases like Alzheimer's and fatty-liver disease, we are hoping to identify big pharma players as our co-development partners, such as how we are working with Johnson & Johnson. Drug development is very time-consuming and costly which is a challenge that would be difficult for GBC to manage alone, especially when the development has to cover so many areas. However, in oncology, this is more manageable to do alone, so we are looking at local partners in different major markets to enter into licensing agreements.

As a botanical drug company, what unique challenges do Golden Biotech face compared to traditional chemical-based pharmaceutical manufacturers?

We have encountered many misconceptions towards botanical drugs when speaking to pharmaceutical companies from the western world. However, since last year we have been able to synthesize antroquinonol, allowing us to treat it as a small molecule rather than a purified extract. Although Hocena® is a botanical drug, we are committed to following all regulatory frameworks of the west. Ultimately, GBC's goal is for our drug to become accepted under the unvisceral standards of drug development.

Golden Biotech has more than 100 patents over 40 countries worldwide with subsidiaries in major markets such as the US, the EU, Japan, South Korea, and China. What is the company's internationalization strategy?

At the moment, these subsidiaries are serving two major purposes; to be our distribution branch in those markets for our functional food product and to act as our center for clinical trials being conducted in the area. In the future, these locations will serve as our new drug distribution centers.

Our ambition is for GBC to become a global pharmaceutical company which can reach patients in need all around the world.

What is the development timeline you expect for Hocena® assuming all goes well?

In lung cancer, we have complemented phase II trials in the US for third line treatment. However, we are designing two more trials to begin later this year as a combination therapy with chemo and immunotherapies. This will be our same approach for treating pancreatic cancer as well since there is currently a lack of effective treatment options.

Our vision is to use Hocena® as a basic supplement to transform cancer treatment into a disease management program. Hocena® with other treatment regimens such as chemotherapy and be used to lower the side effects, allowing for more treatment cycles.

Looking forward, what are your strategic priorities as the new general manager of Golden Biotech?

My challenge and priority is to establish sizeable licensing partnership with a company that can bring our vision of creating a platform treatment to the reality. Currently, our drug development, even in the long-term indications, has a short outlook. Therefore, I want to build a strong base for the company so that we can continue trials long term in areas with high unmet need like Alzheimer’s.

In Asia, it is very difficult to find companies that can pass a 100-year mark. At GBC we feel that it is time for this to change, so we must come up with a long-term sustainability plan. All our indications are fundamental – we are not looking to target niche areas like most Asian biotechs do.

As an experienced leader in this industry, what advice can you offer the younger generation looking to enter into the biotechnology space?

In the biomedical and healthcare related industries, patients are the center of everything. This industry is more about having as long-term plan to help improve the lives of patients rather than to make money quickly. Additionally, finding an expert team in all areas of the business to succeed – meaning not only the product or drug itself, but understanding the market needs, regulatory framework, financing strategy, etc. Having a collaborative spirit with a strong commercial team is

essential. Otherwise even the best technology can be lost in research publications or placed in the wrong hands, never reaching a point where it has an impact on society.

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