Interview: Eugene Huang – Chairman; Hua-Lin Wu – Consultant, Blue Blood Biotech Corp., Taiwan



"BB-101 is the first new protein drug, with its progression from drug discovery, R&D, preclinical study to clinical trials carried out independently by a domestic biotech company in Taiwan."

19.06.2017

Tags: Taiwan, Blue Blood Biotech, Biotech, Partnerships, Strategy

Eugene Huang, chairman, and Hua-Lin Wu, consultant of Blue Blood Biotech

Corp., provide insightful information on BB-101, a protein proven to be efficient for wound healing, while sharing their vision for the future growth of the company through partnerships with big pharmaceutical companies.

Could you introduce yourself to our executive readership?

Hua-Lin Wu (HLW): As a professor in Biochemistry and Molecular Biology in Taiwan, my research interest is in the study of biological functions of the proteins which closely related to vascular biology and wound healing. In the study of the protein expression in diabetic ulcer, we discovered several proteins that are of potential clinical interest. We are looking for the proteins that are up-regulated in the normal wound tissue but not in the diabetic ulcer. Luckily, we are able to identify some proteins of that category which we believed are drug targets for treatment of chronic wound that has critical unmet need.

Eugene Huang (EH): My background is in computer science. However, I joined the company in 2010 with the strong belief in value proposition offered. In line with this, medical needs for diabetic wound healing is continuously growing. As Blue Blood offers the most effective solution present on the market, we believe our medicine will achieve success and be accepted within the diabetic wound healing community.

Can you introduce us to Blue Blood?

EH: Blue Blood is a small company employing 15 people, most of them being part of the research and development department. The capital raised reached 490 million NTD (16 million USD). Our main product is BB-101 protein, which was proven to be efficient for diabetic wound healing, has been approved by US FDA & TFDA (Taiwan Food & Drug Administration). The phase I clinical trial is planning to recruit 24 to 36 subjects, and will be initiated in June 2017. We hope to finish the study by Q2 2018. In most biotech company in Taiwan, the original drug entity is authorized from USA or Europe. Therefore, we pride ourselves on the fact that BB-101 is the first new protein drug, with its progression from drug discovery, R&D, preclinical study to clinical trials carried out independently by a domestic biotech company in Taiwan. In line with that, we are delighted to be developing the protein drug in the country that is supportive and believes in the future of biotech industry.

Blue Blood was founded in 2000. Can you tell us more about the creation of the company? What was the market need that you identified at that time?

HLW: Protein drugs including antibodies, cytokines, growth factors and blood products have a significant share in global market in pharmaceutical industry. The protein products mostly are used to treat cancers, inflammatory diseases, metabolic diseases and genetic disorders. The Blue Blood Biotech Corp. was founded in 2000 aiming to become a hub for engineering and production of protein drugs by bringing together the experts in protein biochemistry, gene cloning, protein purification and fermentation for protein production. We are a few companies that have the skills and capacities to establish the protocols for the manufacturing process of recombinant proteins for pre-clinical usages for customers. After the proteins that can be beneficial for wound healing were identified we started to generate the protein BB-101 and initiated clinical trials. The protein is generated in the normal wound and is necessary for wound healing in appropriated rate. The wound healing assay in animal model clearly demonstrated the benefit of BB-101 in diabetic wound. Since the population of diabetic patients is extremely big and around 15% of the patients will develop ulcers especially at lower extremes the market for the diabetic ulcer is very large. However, the drugs that could be used to promote wound healing in diabetic foot are rare and not satisfied. Therefore, we determined to develop BB-101 as a novel protein for diabetic wound.

Within the thriving Taiwanese industry, we see a great variety of business models, each company striving to fully leverage its human resources and capital. What is Blue Blood’s business model and partnership strategy?

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EH: Currently, we are focused on finishing the phase I trial in Taiwan. At the same time, we are looking for a partner, especially in China due to increasing number of diabetic patients who need wound healing medicine. Besides, there are still no gold solution for diabetic wound healing in China. China will be a good and big potential market for BB-101. We have found a good partner in China. Our partner is really confident about the effectiveness of BB-101 after due diligence. Our partner offers a good business term in order to have business cooperation with Blue Blood. We are confident to be successful in the China market. We plan to go public after finishing phase I clinical trial. New drug development industry is a high-risk industry often lacking resources to support research and development. However, investors in Taiwan are looking to invest in business that is safe. Consequently, our strategy is not limited to finding opportunities only in Taiwan; going public might happen in more mature and opened market. Also, one of our priorities is to attract a professional investor that could link Blue Blood to big pharmaceutical companies. This is important as we don't have a marketing channel through which we can sell our medicine after introducing it to the market.

Let's talk of your R&D pipeline. First, BB-101, for diabetic wound healing. How did you develop this product?

HLW: After the proteins in the wound that could be of therapeutic benefit to the diabetic ulcer were identified we picked one of the most promising proteins for further development. We demonstrated that the protein we choose can stimulate cell proliferation, cell migration and angiogenesis in vitro and in vivo. Most importantly it can promote wound healing in animal models. To simplified the manufacturing process, we then identified the domains of the protein that has the biological activity as the intake protein does. After codon optimization the DNA fragment of the gene was inserted into a vector and transfected into a suitable yeast host. After extensive colon selection procedure, we obtain a yeast clone that has best yield of protein we needed. The protein was harvested and purified from the cultured medium. We are able to obtain the protein of more than 99% purity. The protein product was named BB-101.

What sets this compound apart?

HLW: BB-101 is the product derived from the protein that naturally existed in the wound therefore it was selected by nature to be able to sustain the hazard environment of the wound. Most of the other protein growth factors that have been tried to use in the wound did not achieve satisfactory results could be partially due to their inherited instability in the wound environment. BB-101 is a multifunctional protein. It not only can stimulate cell proliferation and cell migration it potentially can modify immunity response toward wound healing. The BB-101 product has high thermal

stability and is resistant to degradation by many proteases. These biological activity and physical propertied make BB-101 superior characters in compare to other traditional growth factors in wound healing.

Can you introduce us to the rest of your existing product portfolio?

HLW: We also have another protein drug BB-102 for wound healing under development. The new protein drug might have synergistic effect with BB-101 in improving wound healing. The combination of these two proteins drug might provide a best total solution for diabetic ulcer. These two protein drugs potentially can be used to treat other types of chronic wound such as the wound caused by pressure ulcer and deep vein thrombosis.

In addition, we are in the process to develop an antibody against a specific target identified in the wound. The antibody can be used to reduce scar formation. This antibody drug should be very interesting for plastic surgery, especially for keloid patients.

Blue Blood also offers some services to the customers. Can you introduce our readers to your service portfolio?

HLW: A very talented protein engineering team is established in our company to produce the high-quality protein in a very efficient way. With this expertise, we are able to provide protein production service for pre-clinical study. We will provide a one-stop solution for protein production service, starting from gene cloning, codon optimization, clone selection, fermentation optimization and protein purification. We already provided several successful protein production services for customers. Since more and more protein drugs are under development, the profession service will provide a very convenient and effect solution for the customers. The protein production service to our clients can provide some financial revenue for our R&D. It also can provide a good opportunity to collaborate with other companies in the protein drug development.

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In terms of marketing and sales channels, what do you see as the long-term commercial strategy of the company?

EH: We will form a joint venture in China and push our product, BB-101, on clinical trials as soon as possible. And, our China partner will also bring its existing products into the joint venture soon. In doing so, this joint venture will own several products including BB-101 and other diabetic related medicine. At the same time, we are trying to cooperate with cosmetic companies to develop a product for beautiful skin as our protein shows efficiency for quick wound healing on the skin.

Looking forward to opening the channel to increase cash flow for Blue Blood.

As a member of life science community here in Taiwan, what do you envision as critical next steps for Taiwanese biopharmaceutical sector?

EH: Our government wants to develop biotech as our next generation industry. However, this industry needs money and investment. Success of electronic industry has led to people habituating to quick returns and government becoming more conservative. Big companies can invest more money and consequently operate much faster. However, in Taiwan small companies with limited resources cannot prevail among competitors. Those companies are in need of investors who are opened to investing in high-risk industry. I believe mindset adaptation is crucial for development of this industry- accepting high risks and seizing the opportunity of gaining potential high profits as well.

HLW: The bio-pharmaceutical industry is an example of long-term and challenging investment. It also requires great effort to maintain cooperation of experts in different sectors. Taiwan has many very talented and well educated biological and pharmaceutical graduate students and young scientists. It is relatively easy to initiate a small starting company working on a few specific and interesting subjects. Unfortunately, we do not have big bio-pharmaceutical company in Taiwan yet to provide a long support for the efforts. For Taiwanese bio-pharmaceutical industry to be prosperous and successful, joint efforts of our government and private sectors are very critical. By bring together several small starting companies to form alliance, or by forming a virtual joint company we should be able rise to the challenge of Bio-pharmaceutical industry.

What do you see as the most important success factors to ensure Blue Blood will continue to grow in the upcoming years?

EH: The most important factor is continuous research for our protein product. Since BB-101 is a new protein entity, there are still many uncertain properties needed to be confirmed. Based on our expertise in this protein, we believe our team could fully resolve these issues.

As I mentioned before, most protein drug in Taiwan is authorized from USA or Europe, and executed phase II or III clinical trials in Taiwan. These products may face miscellaneous problems after initiating clinical trials. However, they only can obtain document support from authorized company, and it may cause clinical bottlenecks.

Nevertheless, our product, BB-101, from drug discovery, R&D, and preclinical study is all developed by our own technical team. Blue Blood would provide fully technical support if encounter uncertain

issues. This is Blue Blood’s advantageous position, and it is different from Blue Blood and other biotech companies in Taiwan.

Where will the company be in five years?

EH: In five years, phase II clinical trial of BB-101 has been completed, and phase III clinical trial would be initiated. We are confident that the product would be famous in pharmaceutical industry then. Therefore, our efforts in past 5 years would establish recognition in the biotech industry and attracting big pharmaceutical companies to collaborate with Blue Blood. Finally, we expect to achieve success and to be recognised as a pioneer in the protein drug development.

One of the objectives of these reports is to showcase the recent and ongoing success stories emerging from Taiwan’s biotech ecosystem. What do you want our international readers to think about when they hear?

EH: To develop a new drug for treatment of diabetic wound is a huge challenge because there is no efficient drug in currently. And the only one protein drug which approved by US FDA, Regranex, was contributed to increase rate of mortality secondary to malignancy and with poor efficacy. Blue Blood is confident that BB-101 will be an efficacy and stable product for treatment diabetic wounds. In the future, we believe that international biotech industry will thought that Blue Blood is a truly professional company in diabetic wound healing field, and deemed to be a pioneer in protein drug development offering efficiency and strong value proposition.

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