Interview: Tzu-Ling (Karen) Tseng â?? CEO, Bio Preventive Medicine Corporation, Taiwan

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Dr. Tzu-Ling (Karen) Tseng, CEO of Bio Preventive Medicine Corporation in Taiwan, discusses the innovative technology of its patented biomarkers, the success of DNlite and companyâ??s strategy to grow through partnerships with global pharmaceutical companies.

What was your vision when you founded Bio Preventive Medicine Corporation (BPM) in 2014? Can you introduce BPM to our readers?

I established the company in 2014 with the technologies derived from the national biomarker research project that I was in charge at ITRI. I believe in innovation â?? if there was no innovation, BPM would not exist. BPM stands for Bio Preventive Medicine â?? bio as in biomarker. The slogan of our company is *Innovating Better Healthcare* as it is focused on innovation. We develop biomarker-based diagnostics for high-prevalence chronic diseases and oncology. Renal diseases, including Diabetic Kidney Disease (DKD) and renal injury, are our main focuses. Our products are high-value added diagnostics products and IP protected. We are a spin-off from ITRI and we are currently trying to grow the company; series B financing is going to be raised in late 2017. Our goal is to build a world-class clinical stage biotech company and we focus on promoting preventive medicine and reduction of the healthcare burden with biomarker-related technologies.

Can you give us an introduction to your technology portfolio?

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Currently, our focus areas are the complications of diabetes, including kidney and heart complication, as well as renal injury. Our first product is focus on DKD. The trademark of the DKD

related products is â??DNliteâ?•. We deliver DNlite through providing lab service and IVD kit. We already launched the lab service and established the IVD test, while communicating with the US FDA through pre-submission.

The diagnostics of DKD is important as around half of the population with end-stage renal disease (ESRD) have their kidney diseases derive from diabetes. Around 30 percent of patients with diabetes develop DKD. DKD is different than other chronic kidney diseases as the renal function declines gradually. However, the renal function does not correlate with progression of DKD well. Therefore, it is very important to use a new test to identify the development of DKD as early as possible.

Our major focus was on the disease, especially as the prevalence is quite high in Asia. For example, in Taiwan, 44 percent and in Malaysia up to 60 percent of patients are treated with ESRD due to diabetes, which is much higher than in other parts of the world. By comparison, Italy and Switzerland shows a much lower percentage, where only 20 percent of the treated with ESRD due to diabetes. In that case, patients can receive the dialysis. However, the survival rate of dialysis patients with DKD is not very high compared to other dialysis patients with other chronic kidney disease (CKD) and most of cancer patients. As the prognosis is very poor for the diabetes patients receiving dialysis, we decided to develop the technology that can be used for early detection of DKD and prevent patients from dialysis. It also can be applied in terms of evaluating renal efficacy in DKD trials since the disease score derived from DNlite detection is highly correlated with the disease progression.

You launched your first product, DNlite, in 2014. What makes your product better than the competitorsâ??? What is your competitive advantage?

We have two types of DNlite products. The first one is a biomarker panel, another type is a single biomarker based IVD product â?? the DNlite IVD series. Both the biomarker panel and IVD series are urine-based ELISA, which can be applied in most clinical labs. Moreover, we have a worldwide-protected IP and large scale validation. Currently, we are in the process of communicating with the US FDA â?? the dialogue started in November last year â?? and we hope to start a clinical trial by the end of this year. In order to prepare for the clinical trial, we are going to establish our own GMP facility.

In addition to our patent portfolio, we also possess unique strengths in terms of developing biomarker-based IVD. Some of them include high quality clinical specimens derived from well-designed clinical studies, which allow us to not only developed proprietary novel assays but also content/evidence. We already identify several intended uses of our assay, and prioritize our FDA application with various intended uses. Our product is very innovative and there is no existing equivalent on the market. If we are able to receive FDA recognition, we will have a chance to be the leader in this area. One of the major advantages of BPM lies in the fact we possess the worldwide patent. More importantly, our patent is issued in all the major markets and patent scope is correlated with our business scope very well.

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What has been your strategy to boost the growth of BPM?

Around half a billion people worldwide suffer from diabetes. About one third of those patients develop DKD. The early-stage identification of patients who would benefit from the treatment would reduce the healthcare burden. However, our main focus is currently registration with the US FDA, as it is more experienced on the ruling for such an innovative product than its equivalent in other countries. After receiving approval for the clinical trial, we will start application in other countries such as Taiwan, Japan, and Europe. Our marketing strategy will focus on out-licensing, especially in the

US, Europe, and Japan. We have already started dialogues with some companies, but further negotiations will continue after US FDA approval of the clinical trial, as the value of our product will be much better clarified by then.

Nowadays, a lot of companies are trying to develop a new drug for treating DKD patients. Our opportunity is to partner with pharmaceutical companies to enable efficiencies in the drug development process and ultimately speed up clinical trials. Due to a lack of evaluation tools for the renal efficacy of DKD drug development, BPMâ??s technology provides the solution; this is our market opportunity.

For instance, we have entered into a partnership with Boehringer Ingelheim (BI) where DNlite technology is used to evaluate renal effect in a phase IIIb global clinical trial in T2DM patients.

What does it mean for your company to partner with a global heavyweight such as Boehringer Ingelheim?

Our collaborative efforts have led to the improvement and deepening of our knowledge â?? we gained a lot of insights into the disease and treatment. We were not only evaluating the drug efficacy, but also potentially helping our pharmaceutical partner to stratify patients who would benefit from the treatment.

What kind of partnerships do you want to develop? What is your partnership strategy for the future?

BPM deeply recognizes the value of strategic partnerships with companies which share mutual interests in expanding the product pipeline and technology platform for biomarker detection. In addition to co-development, we are looking for international partnership for commercialization. Expanding our business through collaboration with international companies as well as working with the government for reducing healthcare burden with our technology is something we plan to achieve.

Despite being a relatively new company, the maturity of your technology is comparable to that of other organizations with a much longer history. What are your strategic objectives for the upcoming years? What is the next big challenge you want to accomplish with BPM?

Our next challenge is to get regulatory approval. Afterwards, we want to establish our own manufacturing facility and overcome some technical issues in the manufacturing process. Finally, we are thinking about IPO in the near future.

As founder and CEO of the company, what makes you particularly proud about BPM?

I am proud of establishing the leading position of the DKD test. Although competition exists in the market, the performance of our test is superior to that of our competitors. We started developing this test from the discovery phase. Starting from scratch led to worldwide protection and soon will lead to us accumulating a lot of insights of biomarkers and DKD. For example, we observed the post translational modification of biomarkers in urine and its correlation with disease progression. Therefore, we are able to develop products that leave the competition behind and enable us to brand them as high-value added products. Therefore, we are focusing on our R&D capacity and innovation to not only showcase the capability of BPM but the whole Taiwanese innovative ecosystem.

Innovation is the future of Taiwan. If you want to be innovative, you have to take advantage of your own strengths. In Taiwan, the incidence rate of end stage renal diseases is number one in the world. Therefore, we have abundant resources of clinical samples and deep knowledge in renal disease. Taiwan has the potential for developing technologies that can benefit the world and I truly believe

BPM is developing one of them.

What would you like our readers to think when they hear the name Bio Preventive Medical Corporation?

BPM is a leading company in the renal biomarker area. We can help in the development of new drugs not only in the renal area but also renal safety.

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