Polly Lin – CEO, Guzip Biomarkers, Taiwan

Taiwan's advantages lie in our science, technology and innovation performance

11.09.2019

Tags: Taiwan, Biotech, Guzip

Polly Lin, CEO of Guzip Biomarkers, discusses

Guzip's work in epigenetics and the role of DNA methylation in treating endometrial cancer. She highlights the benefits of MPap for women's health and gives an overall assessment of Taiwan's biotech ecosystem.

Ms Lin, you have had a diverse career across the value chain of biotech. Can you please begin by introducing yourself, experience, and journey to Guzip Biomarkers?

I got my PhD in molecular and cellular biology from National Tsing Hua University (NTHU) and then worked in a drug development company for six years as Vice President and RD Director. After that, I started working with Dr Hung-Cheng Lai, a physician-scientist and the inventor of our core technology. Our first project is a smart screening tool for endometrial cancer. We identify a clinical problem on female-specific health and our goal is to provide a technological solution to the unmet medical need. This is why we set up Guzip Biomarkers in August 2018.

As a university spin-off, Guzip's core technology is, of course, its biggest asset. What is the uniqueness of the biosensor technology behind Guzip's IVD tools?

Our product, MPap, is a real-time PCR assay for assessment of methylation biomarkers in DNA. The first-generation product of MPap is intended to be an auxiliary test for diagnosis of endometrial cancer. Currently, tissue sampling, including dilatation and curettage (D&C) or endometrial biopsy, is the golden standard to the diagnosis of endometrial cancer. It requires several times of invasive procedures to identify a real case of endometrial cancer, meaning a lot of unnecessary procedures are currently used.

MPap™ DNA Methylation Detection Kit is the name of your first product under development. Where does this product stand in its development and what commercialization strategy do you have in mind?

For commercial strategy, we have two business models, LDT for service and IVD for products. We are going to launch LDT service by 2019 through a partnership with Shuang Ho Hospital. Regarding IVD mode, we have conducted a multicenter clinical trial in Taiwan. We are expecting to get the TFDA approval and release our IVD product by 2022. I first want to conduct a proof of concept study in Taiwan, and then find a partner to complete development outside of Taiwan or Asia. The world's leading medical device markets, such as the United States, the European Union, and China. Therefore, we are actively seeking licensing and collaborating opportunities in these areas: China, US and Europe. Due to the current specimens are all collected in Taiwanese, we would like to seek for international cooperation for more samples from different races in further clinical research to verify whether if there are big differences between races.

Endometrial cancer, also known as uterine cancer, is the most common gynaecological cancer. However, up to this point, there has been no specific screening tests for this type of cancer. What health impact will MPap™ have in meeting the unmet medical needs that exist in women's health?

Unlike a pap smear for screening cervical cancer, which significantly reduces the death rate, there is no routine and non-invasive screening tool for endometrial cancer. As mentioned previously, the most common symptom of endometrial cancer is abnormal vaginal bleeding. The abnormal bleeding may occur due to several reasons, making the diagnosis of endometrial cancer ineffectively. Usually, these invasive procedures require anaesthesia, and may have a high risk of tissue damage, allergy, infection and blood loss. Guzip provides a methylation qPCR-based screening tool for endometrial cancer, which has a lot of potential to avoid unnecessary and

unpleasant invasive procedures. Our MPap test is easy to operate. We collect cell samples from a routine pap smear, extract DNA and perform the real-time PCR-based methylation analysis. And within only 2~3 days we could tell you whether you are high or low risk with endometrial cancer.

What is the market potential for this product?

The endometrial cancer diagnostic testing market is 2.2 billion in 2019 and it's projected to be 3.8 billion in 2026. According to the 2018 data of globalcan, there are 382,100 incident cases and nearly 90,000 women died because of it. The number of newly diagnosed women is expected to grow by 70 percent, reaching 583,600 in 2040. We do have competitors on the market. A competitive analysis allows you to assess your competitor's strengths. Overall, our sampling method is much easier and the result is much faster with high accuracy and also cost-efficient.

Just within the company's first year, Guzip has attracted attention in international startup competitions like the Bridge to MassChallenge and Bayer's G4A accelerator program with H Spectrum. How have these achievements played a role for driving development?

These accelerator programs offer us mentorship programs and gave us the opportunity to explore more, which we could introduce our company and showcase our product. Indeed, raising patients' awareness is crucial to reduce the incidence of the disease. During these different programs, our main focus is on raising awareness of the importance of endometrial cancer in women.

How would you assess Taiwan's market and biotech ecosystem?

Taiwan's advantages lie in our science, technology and innovation performance. We team up with Taipei Medical University and Shuang Ho Hospital and aim to create an ecosystem of gynaecological health care in Taiwan. US and Chinese startups don't need to worry about going global right away because they have a good-enough market at home. Taiwan's tech-people do offer an excellent starting point for early-stage companies, but the market is too small for local companies to scale up, which enforces startups to look for investors abroad, in order to get the investment. I think that it's a complex and difficult environment right now, that's why we need to build our own ecosystem. As far as Guzip is concerned, we just finished our seed funding in March

this year so our cash flow is steady.

What are your current strategic priorities to lead Guzip further in the company's journey to market launch?

We have significant progress in the LDT (laboratory-developed test) service in the past few months. LDT is a diagnostic test that is designed, manufactured and used in a single lab. Additionally, we are processing the IVD (in vitro diagnostics) developing a plan from product development, design control processes, quality systems, GMP, etc. Currently, a multiple centre clinical trial to validate this product is ongoing. Moreover, a single product company is riskier than companies with a variety of products, so we would like to enrich our pipeline with new relevant research projects in the future.

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