Interview: Chih-Yi Weng â?? Chairlady & CEO, Charsire Biotechnology, Taiwan

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Chih-Yi Weng, chairlady and CEO of Charsire Biotechnology, one of Taiwanâ??s leading biotech companies focused on the development of botanical new drugs as well as topical and personal car

e products, provides insights into the companyâ??s unique business model and its promising and maturing R&D pipeline, while Charsire was ranked in 2015 by Deloitte as one of the fastest growing life sciences companies in Asia Pacific.

Could you introduce Charsire Biotechnology to our international readers and document the vision that has been driving its development since the companyâ??s creation, in 2002?

Over the past fifteen years, Charsire Biotechnology has conducted many in depth pharmacological experiments on full-thickness skin wounds and has been investing tremendous efforts in the research and development of botanical new drugs, while our R&D pipeline now holds three very promising new drugs. In this regard, Charsire truly stands as an innovation-driven, new drug development company focused on bringing life-changing products onto the global stage, while we focus on unmet medical needs.

Nevertheless, our business model and development approach are very different from these of most other Taiwanese biotech companies, which usually exclusively rely on the stock market and institutional investors to move their R&D pipeline forward. In order to generate the substantial resources that new drug development activities require, we have indeed developed three main platform technologies in the areas of Regeneration, Circulatory Disturbance, and Anti-Inflammation

â?? and accordingly derived a premium portfolio of botanical skin & personal care products, whose rapidly increasing revenues have been fueling our R&D ambitions. This two-fold approach, where the marketing and sales of skin and personal care products is nurturing the development of our botanical new drug pipeline, has allowed us to remain an independent, privately-owned company, while developing our capacity throughout the entire value chain, from R&D to marketing and sales â??without the help of any major VC fund or other institutional investors.

Since their launch onto the Taiwanese market in 2003, we have sold more than one million tubes of our in-house developed, botanical skin and personal care products, leading Charsire Biotechnology to be recognized in 2015 as one of the fastest growing life sciences companies in the region by Deloitteâ??s Technology Fast 500 Asia Pacific ranking. Additionally, the sales of these products also allowed us to massively access and collect a large number of usersâ?? experiences and feedbacks, which later motivated us to aim for receiving the scientific approval of the US FDA.

As a matter of fact, in 2013, the US FDA approved our first new drug, CSTC1, for diabetic foot ulcer wound, to enter phase II clinical trials. In 2015, Charsireâ??s second new drug, ACA, a pain reliever for radiotherapy in head-and-neck cancer also received the green light from Taiwan FDA to advance into the stage of clinical trial stage; while in 2016, our Alzheimerâ??s disease and vascular dementia new drug, BAC, received approval by the US FDA for a phase II trials too.

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Besides providing Charsireâ??s new drug development arm with the resources it needs, how does this two-fold business model stand as a competitive advantage within the development strategy of the company?

Since the company was established in 2002, we have been favoring a long-term development vision, where Charsire would steadily develop its in-house capacity in a comprehensive way, rather than simply leveraging investorsâ?? money to develop new products. For example, by handling the marketing and sales of our skin care products in Taiwan, Charsireâ??s executives and employees have been accumulating a particularly valuable experience in terms of product development and marketing, which will be extremely useful when bringing our botanical new drugs onto the global market. More importantly, our commercial footprint in the botanical skin & personal care series provides us with a direct access to usersâ?? feedbacks and a better understanding of their needs â?? which we can now leverage when designing the specificities of our botanical new drugs.

The rapidly increasing sales of our skin & personal care products in Taiwan also encouraged us to expand our geographical reach. In this regard, we recently established a sister company in Singapore, which will handle the marketing and sales of locally adapted, new formulas of our existing products under a different brand name.

Our increasingly popular skin & personal care products also provided us with the opportunity to develop a cutting-edge manufacturing arm. We indeed established our in-house R&D center to ensure the QC standards in all extract of formulas, and, in 2013, completed the construction of our PIC/S GMP production facility, which received TFDA approval in 2015. In addition, we overhauled the manufacturing nuts-and-bolts from planting to pharmacological and safety researches to manufacturing control throughout the entire production line, which is now ready to manufacture both botanical cosmetic and our upcoming new drug development products, meaning our company can control the quality of its products from their conception to their manufacturing and sales.

How does this independent, integrated develop approach trickle down to the R&D level?

While some Taiwanese biotech companies have chosen an NRDO (No Research, Development Only) model and/or mainly rely on venture capital or private equity fundsâ?? financial support, Charsire both holds its own, in-house R&D center where our researchers have been producing a very large amount of pre-clinical and pharmacology studies prior to initiating the clinical development of our products, while we moreover paid very close attention to uphold our financial independence. In this regard, Charsire â?? once again â?? differentiates itself from the rest of Taiwanâ??s biotech companies, which usually rush into clinical trials as soon as they hold interesting preclinical data, while we always make sure to hold very robust preclinical evidences before entering into the clinical stage.

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â??The Gears of Charsire.â?? Source: Charsire

One of Charsireâ??s cornerstones is its own proprietary technology of natural plants extraction in Cell Regeneration, Anti-Inflammation, and Circulatory Disturbance, which were successfully patented in the US, EU, in Japan and China â?? among many other countries. Through years of experience in the marketing and sales of our personal care products, Charsire has broadly documented topical transdermal resorption experiences from users and moreover been able to accumulate a very deep understanding of our productâ??s efficacy on humans, which should not only ensure our R&D strategy is heading to the right direction but also reduce our risk exposure and strengthen our confidence in our productsâ?? capacity to be successful in phase II clinical trials.

Looking at your R&D pipeline, could you provide insights into the development of CSTC1, Charsireâ??s botanical new drug for diabetic wound?

In the early 2000s, Charsireâ??s founder, Mr. I-Hung Chu, started conducting comprehensive animal regeneration studies in full thickness skin tissue wound healing and partial deep second degree burns, whose results clearly highlighted that CSTC1 held the potential to tremendously accelerate wound healing. Based on the same technology platform, we subsequently launched a very successful series of skin & personal care products, whose excellent customer feedback further convinced us to engage in the clinical development of CSTC1.

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In 2013 and 2014, CSTC1 received approvals by both the US FDA and Taiwan FDA respectively to enter clinical phase II trials, while the overall clinical development of this product â?? our first new drug â?? stands as crucial learning experience for our company. For CSTC1, we decided to concentrate its clinical development in Taiwan, where we started a phase II clinical trial in 2014. We look at enrolling 125 patients for this crucial trial and plan to complete it by the second quarter of 2018.

Regarding our collaboration strategy, we chose to exclusively invest our own resources to conduct this trial and to start looking for external partners once we will get our phase II data. As just mentioned, our animal studies and the usersâ?? experiences from our skin & personal care applications make us particularly confident the clinical results of our phase II clinical trial will be extremely positive, which should further enhance the commercial value of our product and help attract investors and partners for the next steps of its development.

Given its healing potential, why did you decide to focus on diabetic wounds for CSTC1?

In many advanced markets, diabetes stands as one of the fastest growing diseases. In the US, where it remains the seventh leading cause of death, recent studies estimated that half of adults

have diabetes or pre-diabetes while around ten percent of them holds high risks to develop ulcers.

Diabetic ulcers are life threatening, full thickness wounds that do not present any external or blood circulation symptoms but display extremely high infection risks. Over the past years, RegranexÂ®, a product based on Platelet-derived growth factor (PDGF) â?? one of the numerous proteins that regulate cell growth and division â?? has been widely used for diabetic wounds in the US, despite safety concerns which prompted the US FDA to issue a public warning regarding its safety. As a result, despite huge market needs, there is no truly satisfactory and safe product available to patients and physicians at the moment.

According to our current observation, CSTC1â??s healing ratio for grade 3 diabetic wounds could be up to 90 percent after only eight weeks, which is far better than PDGF based drugs, which display a healing ratio of around 50 percent after 12 weeks.

Furthermore, CSTC1 is highly safe and can be applied in large area of wounds ($50cm^2$), while it has great potential to become a frontline therapy in this indication.

What about the rest of your new drug portfolio?

We hold two other very exciting products in our pipeline, which were both discovered in our in-house R&D center and developed thanks to our companyâ??s three proprietary technologies in the new drug development model platform.

In the anti-inflammation field, ACA, is a pain-relieving, new adjuvant drug for head-and-neck cancer radiotherapy. It targets all kinds of discomfort, especially pain and dermatitis, caused by cancer radiotherapy, with the objective to increasing treatment efficiency, patientsâ?? adherence to their treatments and improving quality of life. For example, our animal pre-clinical studies showed that skin tissue was fully repaired, and micro vascular tissue as well as hair follicles were successfully regenerated in ACA treated group, while â?? in the control group â?? skin fibrosis had started to form, hair follicles were damaged and hair growth was altered after irradiation.

Looking at the circulatory disturbance field, BAC, our promising product for vascular dementia and Alzheimerâ??s disease, has already received approval by the US FDA for a phase II clinical trial. One of the key specificities of this product lies in its dosage form: BAC is a topical application drug, while all other pharmaceutical companies active in this field are concentrating their efforts on oral drugs. As a topical product, BAC will then hold the great advantage to be easily combined with other oral products taken by patients. Only three months after we initiated our phase II trial, we are particularly glad to see that patient recruitment has been progressing extremely rapidly, as 20 patients out of the 60 needed for this trial have already been enrolled.

As for all our other products, we based our decision to move forward the clinical development of BAC on the great outcomes we identified in our human experiences, including the feedback from customers of our topical skin & personal care products, where we saw BAC could significantly improve the cognitive capacities of elderly people. We also conducted two different kinds of pharmacology studies on animals, in heavy metal induced Alzheimer like pathologies and bilateral occlusion of the common carotid arteries induced vascular dementia, whose results showed BAC could improve the cognitive capacity of the studied animals.

Finally, we also hold promising compounds at the preclinical stage, which could soon enrich our R&D pipeline. Although I cannot disclose any additional details about these exciting products, we will however remain loyal to the companyâ??s historical development approach and ensure we hold very robust and convincing preclinical data prior to moving these products to the clinical phase.

Charsire was founded fifteen years ago with the vision to develop innovative, botanical new drugs. The company now holds three promising products undergoing phase II clinical trials; what do you want to achieve within the next five years?

Our first and foremost priority is to advance the clinical development of these three new drugs, with the ambition to conduct phase III clinical trials and receive US FDA NDA in collaboration with experienced, international partners that share the same values as our company.

In terms of new product development, Charsireâ??s R&D strategy is very clear: we focus on unmet medical needs and will tirelessly strive to bridge the gap between patientsâ?? needs and existing therapeutic options. With regard to our business vision for the next five years, we believe each talent we hold at Charsire is a very important pinion steadily moving the wheels of our three proprietary technologies forward. Starting from 2017, Charsire will also actively promote a new branding of skin & personal care products in South Asia and Asia Pacific regions. Finally, A plan for an initial public offering (IPO) in Taiwan will also be kicked off soon to attract more abundant business resources and to accelerate our R&D momentum.

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In the grand scheme of things, I want to highlight that Charsireâ??s ongoing success story has become possible thanks to our countryâ??s limitless efforts to build a world-class R&D environment for biotech companies. Charsire can now leverage Taiwanâ??s unique talent pool in this field and the top-notch quality of our medical, clinical and scientific infrastructure to fulfill our international ambitions.

As our productsâ?? development is rapidly advancing and our R&D pipeline is maturing, we are now looking for partners that are eager to leverage Taiwanâ??s biotech capacity and Charsireâ??s expertise in the botanical new drug field to jointly bring life-changing products onto the global stage.

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