Interview: Dr. Karen Wen – President, Mycenax Biotech, Taiwan

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The co-founder and president of Mycenax Biotech, Dr. Karen Wen details the key lessons learned from the development of their first in-house product TuNEX® and how they have been applied to their second flagship product LusiNEX (tocilizumab). She also details the company's transition from a platform-driven service provider to a product-driven player, underscoring the significance of their traditional capabilities in chemical, manufacturing, and control (CMC) as a value-added asset and key differentiating factor for their partners in the biologics space.

In June 2016, the results of two phase III trials provide clear evidence of TuNEX®'s efficacy and a few months later, at the end of December 2016, you signed a ten-year, drug authorization distribution contract with Orient EuroPharma, spanning nine countries in Southeast Asia. Congratulations! Beside the economic impact for the company, why are you particularly proud of these two achievements?

As Mycenax is a primarily CMC based company, TuNEX® effectively highlights our product development capabilities. This is our first product that we created from scratch to have successfully filed for a new drug application (NDA). More significantly, TuNEX® also stands as Taiwan's first biopharmaceutical product, while it will soon become our country's first biological drug to reach international markets. Our marketing campaigns will begin first in Taiwan, then spread out to ASEAN, and eventually across the Pacific to Latin American, the US, and other Western markets.

We've learned a lot throughout the entire development process—not just the chemicals, manufacturing and control aspect—teaching us invaluable experience that we are now applying to the development of our second product, LusiNEX, which we intend on receiving IND approval for this year. This time around, however, we will introduce the product in more dominant pharmaceutical markets such as Europe or the US first before gradually branching back towards developing markets.

Simultaneously, we are also currently negotiating with a Japanese company to bring them on as a potential joint-development partner.

The biosimilars segment is still in a very early stage of development in Taiwan, with many years left before reaching critical mass. This has warranted a more cautious approach from players like Mycenax when developing and launching new products, as was the case with our first product, TuNEX®. But now we're familiar with the development scheme, while acquiring a high degree of confidence in the product-market fit; customers are demanding an effective product, with pristine quality and a competitive price—all qualities that LusiNEX boasts, which in turn, allows us to initially target the larger, more established markets with assurance.

Perhaps underscoring these milestones, it is also worth touching upon the sheer level of complexity and sensitivity involved in biologics manufacturing, especially when compared to small molecules. Any divergence in the manufacturing process, however miniscule, can result in a completely different end product.

Can you elaborate on the primary learning points from your experience developing your first flagship product TuNEX®?

The primary learning points lie in the design of the process and clinical trials. TuNEX® can be considered a "semi-biosimilar." We tried developing a completely new drug, but realized this route was extremely capital intensive and time consuming.

Taking these learnings into consideration in the case of LusiNEX, we already knew the standards that would warrant a "real biosimilar," in terms of design and testing, clinical efficacy and outcomes. Furthermore, obtaining EU or FDA approval became a critical first step, which, for biosimilars, has proven to be a rather longwinded and complicated endeavor in and of itself. The second stage then focuses on targeting the Japanese market, which is very receptive to such new technologies but not me-too driven. We are now seeking for big pharma partners for the further development of LusiNEX, but specifically after phase I, which we expect to start in Q2 2017.

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With TuNEX® now released in the market, how would you project its demand prospects?

TuNEX® is a semi-biosimilar version of Enbrel—a prescription medicine targeting autoimmune diseases with substantial market share worldwide. Given Enbrel's existing level of penetration, we would aim for some percentage of its existing market share to justify a return on investment. Needless to say, the market potential is very significant.

Can you explain the Mycenax's due diligence process when it comes to identifying and bringing new compounds into your portfolio?

We look into the market, the intellectual property, clinical capabilities, and how long before we're able to obtain a return.

Additionally, our capabilities are specifically centered on CMC, so we would need to determine where we could add the most value along the compound's development and manufacturing pipeline, if at all.

Many of the big pharma companies possess their own team of clinical researchers to advance their portfolio. Our model, on the other hand, relies on effectively pairing our CMC expertise with the capabilities and talents of our partners or joint venture parties.

When we find external partners, we not only bring our capital, but also our experience and insight to become a truly added-value complement.

The development of an in-house pipeline is actually somewhat divergent of the company's initial roots. What direction can we expect Mycenax to take from this point forward?

To solely remain as a CDMO player would require a significant expansion of our facilities and substantial capital investments. However, we determined that the market would not be suitable for this added scale, as many countries in the region such as China, Korea, and Japan have the ecosystem for a thriving biotech scene that encourages the growth of local manufacturer. Ultimately, the main issue we identified was not price, but market—thus warranting our transition towards becoming a product-driven company.

Platform-wise, we still very much maintain our competencies as a CDMO service provider, constantly controlling the critical supply of key materials, while maintaining the highest standards in quality at a competitive price point. Uniquely, our plant utilizes disposable components, which,

compared to the traditional large stainless steel bioreactors, allows us to not only much more easily reconfigure our floor plays to accommodate different technology transfers, but also replicate our layouts in any setting that we choose to go.

But as mentioned, expanding these facilities is not our main priority at the moment; given our new strategic course, the scale of our manufacturing plant is already suitable for our current and future operating capacities.

In terms of effectively shifting towards a product-driven company, we need to figure out how to best utilize Mycenax's existing assets, specifically our manufacturing equipment and technology, while identifying the most appropriate products and indications that would appeal to our user base — the clinicians.

Thankfully, we have been able to leverage our existing CMC capabilities to make a relatively seamless transition into new drug development, particularly when complemented by the competencies of joint partners. Consequently, we are also able maintain a degree of flexibility when it comes to our therapeutic focus. For example, we currently hold rights in a product from a company targeting bone repair, while simultaneously exploring another potential project with a different company solely focused on immunomodulation—both of which leverage our CMC services for development. And the experience that we're able to take away and insight that we're able to gain from engaging with clinicians during this entire process are invaluable—as was the case with TuNEX®.

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In terms of enhancing the company's value proposition, where will your priorities lie in the next three to five years?

In the coming years, we will focus our efforts on introducing TuNEX® into more markets across the region, especially given that the second generation of this product is now available.

Additionally, LusiNEX will be advanced in the clinical studies in major markets with global or regional partners.

At the same time, more new drug projects will be incorporated in, including the ones with joint venture model.

For new biological entities, we are currently evaluating two product candidates and essentially verifying their clinical efficacies and intended outcomes. After undergoing the proper due diligence

and verification, either licensing-in or joint ventured will be the options.

Ultimately, I hope to position Mycenax as a manufacturing center, but concurrently serving as somewhat of a venture capitalist that not only invests in a broad portfolio of companies pursuing new drug candidates.

Our vision is underscored by our company's slogan *"From the bench to a better life".* If there are companies with good biologic candidates that want to effectively advance the development timeline, then Mycenax is the partner of choice.

As one of the founders of Mycenax, what factors ultimately motivated you to start your own business?

When starting this company in 2001, my sole purpose was just to learn something new and with promising. Under the guidance of different mentors, teachers, and advisers, I soon began to truly manifest my entrepreneurial ambitions as we began overcome various obstacles and achieve one milestone after another.

Initially, I was content with just getting TuNEX® onto the market and the moving on to the next opportunity. Now, however, as the company continues to grow, I am truly excited about the learning opportunities that Mycenax brings to not only myself, but also the younger generation. Inspiring those individuals to get more involved in this industry is a truly fulfilling experience for me.

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