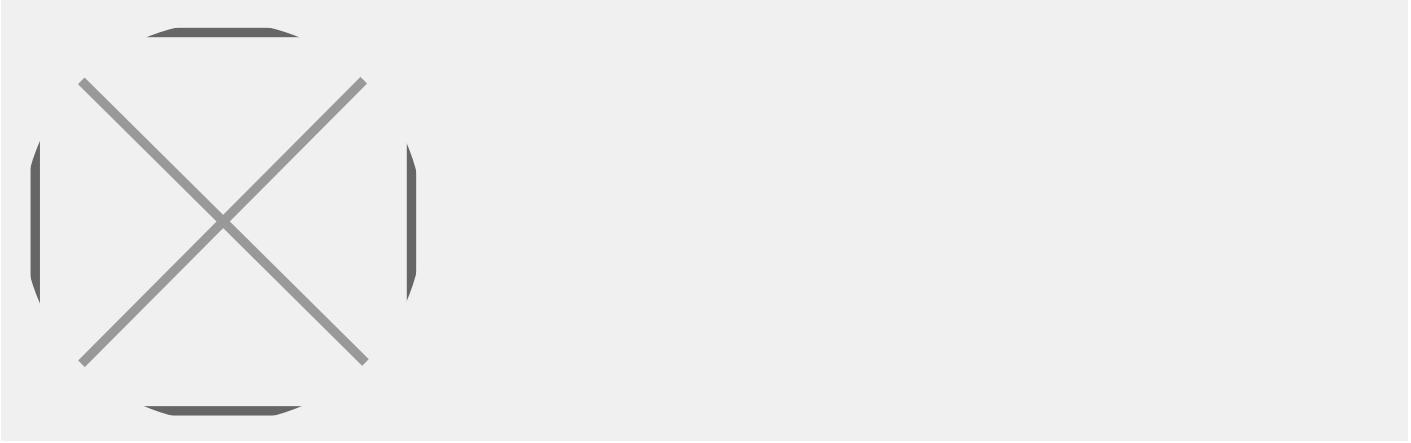
Interview: Ming-Chu Hsu, Chairman & CEO, TaiGen Biotechnology, Taiwan



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TaiGen is on the brink of releasing Taiwan's first innovative drug. In this interview, the Chairman and CEO of the company discusses the development path the company chose to take, and explains the decision to market the drug first in China.

Nemonoxacin will be the first-ever pharmaceutical developed in this country to meet the Chinese Food & Drug Administration's (CFDA) Category 1.1 New Drug requirements. What can you tell our readers about this remarkable milestone?

Indeed, Nemonoxacin is a hugely significant milestone for TaiGen. But it is more than TaiGen's milestone: our work on the product has ushered in a new mode of drug development in our region.

TaiGen's goal has always been to cut into the rapidly-developing Chinese market, as fast as possible. Of course, for a Taiwanese company, the costs of going to China are far lower than penetration of the US or EU markets. Every one of the drugs we have under development is geared for the global market—nonetheless, our initial focus is China, where we feel we have the resources to compete. We will expand elsewhere in the world through strategic partnerships.

One of the big advantages a company like ours has in cutting into this neighboring market is our knowledge of the culture and language. However, the environment in China, relative to the US and EU, is considerably less mature. As the pioneer in this area, we must essentially build the road ourselves. Today, I can confidentially say that we have achieved our original goal: to cut into the

Chinese market with an innovative drug that enjoys full patent protection worldwide.

TaiGen currently has three major pipeline projects. The first is Nemonoxacin, which is now in the New Drug Application (NDA) process. Nemonoxacin marks the first-ever instance of a drug that underwent a US Phase II trial but filed its first NDAs in China and Taiwan. Compared to other international companies that are looking at drug launches in China, we are moving at a much faster speed, and at much lower cost.

The Chinese pharmaceutical market will become the second largest in the world by 2016. However, with a population that is four or five times the size of the US, even then China will have a great amount of room to grow and grow. China's economy continues to develop, and history tells us that when peoples' lives improve, one of their expectations is that their access to quality healthcare improves. China is a very lucrative market for TaiGen, and we have positioned ourselves as a regional leader in new drug development—but the road to development in this region is not as clear as it is in the West!

Why do you say that?

The regulatory agencies have never dealt with so-called 'innovative' drugs before. When I first met with the CFDA, for instance, their thinking surprised me—they seemed to be entrenched in a very generic-style approach.

In Taiwan, the Executive Yuan announced last year that any innovative drug that is developed in Taiwan will be fast-tracked into the National Health Insurance program, with favorable pricing. Nemonoxacin will be the first such drug, and we have held discussions with the BNHI regarding how the agency will calculate price. In Taiwan, until your drug receives a price, you cannot start to market it; the situation is different in China, where you can start to market a product directly after approval. But in both cases, the local origin of the new drug will ensure that authorities work with us to offer a favorable price point.

Did the Economic Cooperation Framework Agreement (ECFA) between Taiwan and China change the game for you?

TaiGen did not enter the drug development business, with an eye towards China, in anticipation of ECFA. ECFA has been in place for only three years, whereas our work began more than a decade ago—we were well ahead of the agreement. In the absence of ECFA, our strategy would remain the same.

China first developed the guidelines for a Category 1.1 new drug in 2003/2004. Under 1.1, they offer companies incentives to develop drugs in the country. Chinese authorities knew they had created an interesting offer—if Taiwan, conversely, wanted to incentivize businesses to come here and develop innovative products, few pharmaceutical companies would accept because of the small size of the market. China, being a huge country, has a much more viable case to make.

TaiGen is the first so-called 'foreign entity' to complete a Phase III trial in Taiwan and China, according to 1.1 requirements (our Phase II study was carried out in the US, South Africa, and Taiwan). But China introduced the 1.1 incentives in order to bring up their R&D standard—and to this end, they have also required the drug to be not only developed, but also manufactured, locally.

And TaiGen has recently taken on a production partner in China.

That's correct.

What's next?

Nemonoxacin opened not only a new mode of innovative drug development in this region, but for our company, it opened the door for new products. We already have a second drug approved for clinical trials in China under Category 1.1 guidelines. The authorities are now encouraging us to submit a third drug under the same scheme.

Each of our drugs has critical medical need for Chinese patients. Now that we have built up credibility with the CFDA, and earned their confidence, they will exempt a number of barriers so that we can move forward faster. We achieved this strong relationship by working very closely with the regulatory agency and ensuring that they understand the way we work. The benefit has been mutual: along the line, I believe that they have learned a lot from us.

The CFDA is now acquiring the experience they need to improve their work. Compared to the US FDA, the agency is extremely new and very small. The only way to build up your experience, of course, is if you have cases to work on. It's a chicken-and-egg situation—but for our second drug, we received acceptance into the 1.1 scheme very quickly. Our third drug should move even faster.

Is TaiGen's vision to ultimately become an integrated pharmaceutical company?

This is indeed our dream. Currently, we do not manufacture drugs ourselves—we use partners. Nemonoxacin will require at least 300 sales and marketing personnel to be marketed effectively in China, and we will outsource this activity to a partner as well. But in the near future, we will build up manufacturing capacity, and we will build up marketing capacity.

From an internationalization perspective, as I noted previously, we will initially focus on China, and export finished product to other countries. Taiwan’s regulatory framework has followed developments in the US, and therefore, regulatory approval in Taiwan is quite significant, and opens doors around the world. We will fully utilize the opportunities we see in Taiwan and China—then we will think about expanding further!

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