Using Partnerships, Hua Medicine Brings Novel Diabetes Drug to Phase III

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Li Chen, PhD, co-founded Hua Medicine (Shanghai) six years ago with Ge Li, PhD, founder of WuXi AppTec. The company soon in-licensed global rights to a GKA treatment for type 2 diabetes from Roche. Late last year, Hua announced positive results from the candidate's proof-of-concept Phase II trial. The company also raised $50 million in additional capital during 2016 and has started US clinical development of the GKA candidate. Dr. Chen, who was previously CSO at Roche's Shanghai R&D Center, talks about Hua Medicine and the contribution of the ChinaBio® Partnering Forum to China's drug development ecosystem. The 2017 ChinaBio® Partnering Forum will be held May 31-June 1 in Zhuhai, China.

ChinaBio: Dr. Chen, Hua's lead candidate is an oral GKA treatment for diabetes. It recently completed a Phase II trial in China. Can you tell us more about where you are with the candidate?

Dr. Chen: We expect our GKA candidate will be a first-in-class and, based on data from the Phase II trial, probably best-in-class oral type 2 diabetes treatment. The Phase II data is excellent, and we will be starting the Phase III trial later in 2017.

ChinaBio: What's next for the GKA drug after Phase III and, hopefully, approval?

Dr. Chen: Hua will be responsible for China commercialization and marketing. After approval, there are still a lot of things to do. We will need some way to identify patients with type 2 diabetes and then find an approach to them. Outside of China, we plan to co-develop and co-promote the drug there.

ChinaBio: You are also conducting clinical trials in the US.

Dr. Chen: Yes. The US is a very different market. In the US, the diabetic population takes metformin as a first-line treatment. So we administered our GKA treatment as an adjunct to metformin and the results were excellent. Because most China type 2 diabetics are treatment naive, we tested the drug as a monotherapy there. We saw excellent results in both countries.

ChinaBio: How does the ChinaBio® Partnering Forum fit into your strategy?

Dr. Chen: The most important role for the ChinaBio® Partnering Forum is to bring everybody together and allow our industry to develop. Most importantly, it brings investors together with innovators, entrepreneurs. For us, we are a small company, with about 30 to 40 people. We need a large community of 500 to 600 people in the medical and scientific communities to support our clinical research. The ChinaBio® Partnering Forum makes the community aware of us and helps us work with the larger ecosystem. It brings people together and provides an environment that allows the industry, all aspects of the industry, to develop.

ChinaBio: Are you in the hunt for additional drug candidates?

Dr. Chen: Our strategy is that, while we continue to develop and then launch our diabetes drug in China, we are talking to pharma partners and we open discussions about their potential portfolio molecules that Hua could license. In the future we would like to become a company that offers China market operations with partnerships in other regions. We could also co-promote products together outside of China.

There are several discussions underway currently. This is very exciting.

ChinaBio: Why does Hua adopt the China marketing/Ex-China co-promotion model?

Dr. Chen: Hua will do well marketing our own drugs in the China market because of our expertise and influence. Then, while we are working with partners outside of China for our drug development, we might also seek to license China marketing rights for their products. Using this model, both parties will be leveraging their strengths and partnering to benefit patients and the companies.

ChinaBio: What kind of partnering do you do in China?

Dr. Chen: We use a very innovative model here in China. We call it Collaborative Innovation. Hua has a strategic partnership with WuXi AppTec and its affiliated companies in the pre-clinical space, clinical development and contract manufacturing. Also we are working very closely with global CROs like TigerMed and dMed and a few others, working on clinical development and preparing for pharmacovigilance, monitoring and preparing for NDA approval. We have been working with over 30 partners in the areas of early discovery early development and commercialization/ manufacturing and then clinical development. Obviously, Hua will develop marketing skills through a partnership-based relationship.

ChinaBio: How did the GKA candidate perform in the China Phase II trial?

Dr. Chen: In the Phase II test, 268 diabetes patients received the treatment for three months on several different regimens. The efficacy was really great, lowering average HbA1c levels by 1.2%. The results were very significant with a p value of 0.01. Side effects were fairly benign -- relatively little hypoglycemia for example -- and in line with other oral type 2 diabetes treatments. It's a good drug. Ours is the first successful trial of a GKA drug. Earlier versions caused hypoglycemia and often lost efficacy fairly quickly.

ChinaBio: When do you expect to put your GKA diabetes drug on the US market?

Dr. Chen: We have a plan for getting our partners ready in 2018-2019 and that's where we will engage the US NDA trials. And then probably, it will take a few years to get through the trial and the drug will be ready to be launched around 2022-2023.

We want to help patients and the current drug is not very effective. There have been a lot of drugs brought to market since insulin was developed 100 years ago. Insulin makes sure that people don't die from diabetes. But look at the disease: it's increasing. The current drugs do not cure people. New patients are diagnosed while the older patients are still there. Fundamentally, the community has not been able to target the cause of the disease, but they work to simply lower the blood glucose level to acceptable levels. Their drugs target symptoms, not the cause of the disease. That's where our drug is different. It targets the underlying cause and that's why the clinical benefit is so big [*Ed.* -- Hua's 4th-generation GKA targets a key enzyme (GK) that acts as a glucose sensor and regulates carbohydrate metabolism. It was designed to avoid the side-effects of previous generation drugs]. We can talk more about that as we complete our Phase III trials.

ChinaBio: We talked, back when you were just starting Hua, and you said it was the perfect time to start a China innovative drug company. Were you right about that?

Dr. Chen: Yes, I think so. Basically at that time we said we wanted to be the most innovative biotech company in China and be able to offer first-in-class, best-in-class drugs for patients worldwide in exciting therapeutic areas. We just did that.

And the other part I said was that in China the regulatory and financial environment would improve, and that has also taken place. In the last few years, the CFDA has put new policies in place encouraging innovation and enforcing quality of marketed drugs and clinical trials. They are bringing the whole process of drug discovery and innovation level up to the level of the US and Europe. I think that's a major step forward and Hua benefits from that.

Also, also the investment community is very much involved in drug development. In 2016 a huge amount of investment was made primarily to China innovative drug companies,

mostly coming from China-based venture and PE funds. Significant progress I'd have to say, and it seems like what we predicted six years ago is coming true.

ChinaBio: Dr. Chen, congratulations on Hua's success so far and thank for your time.

Disclosure: none.