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Hua Medicine Advances Diabetes Treatment toward Trial

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Hua Medicine is on track to get its first drug candidate into clinical trials. The molecule is a treatment for type 2 diabetes in-licensed from Roche (SIX: ROG) (see story). Hua filed a request for Clinical Trial Approval in September, and it completed its Site Inspection and Dossier Amendment this week – a process that took only one month instead of the usual three-to-four months. According to Hua, the "well-established drug innovation ecosystem" at Zhangjiang High-Tech Park and its own Collaborative Innovation model of drug R&D were the reasons the drug is advancing so rapidly.

Hua began its operations just over a year ago. The company had immediate credibility because it was co-founded by Li Chen, PhD, who established Roche's R&D program in China, and Ge Li, PhD, the founder of WuXi PharmaTech (NYSE: WX). It also had $50 million in funding, drawn from an A-list of venture capitalists: Arch Venture Partners, Venrock, Fidelity Biosciences, Fidelity Ventures Asia (China) and Shanghai Alliance Investment Ltd. WuXi PharmaTech's investor arm also participated.

In 2011, ChinaBio® Today published an exclusive interview with Dr. Chen, the company's CEO as well as its Co-Founder, who discussed Hua's business plan in the context of his belief that now is the best time to be starting a China drug development company (see story). Dr. Chen said Hua would be partnering much of its drug development work. But he strongly resisted the label of "virtual company." He said the company would eventually have 60-80 employees, who will be active collaborators with its partners.

The new diabetes drug, which Hua calls HMS5552, is a glucokinase activator (GKA). It is a novel, small molecule activator of the glucokinase enzyme, which helps to regulate carbohydrate metabolism.

a previous generation of GKA compounds, Roche showed in the 1990s that GKA drugs can lower blood glucose levels. Unfortunately, they also sometimes caused hypoglycemia. Roche believes the latest generation is both safer and more effective.

For Hua, the business plan is to bring "breakthrough" innovative drugs from the West to China. It is looking for 2-3 candidates that have already been approved in the West or are ready to enter the clinic, and another 2-3 earlier-stage molecules that must undergo pre-clinical development. In addition, Hua wants to start its own innovative drug program. Its rapid progress toward a clinical trial of its first candidate shows that Hua can execute its plan.