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China's Green Channel Significantly Shortened Filing Time For Start-up Hua Medicine

Start-up Hua Medicine says IND filing time using China's green channel shortened the review process at the provincial level.

SHANGHAI – Chinese start-up **Hua Medicine Ltd.** announced that its first in-licensed compound, **Roche**'s glucokinase activator (GKA), has passed provincial FDA inspections in half the time it normally takes by leveraging the fast-track green channel for locally developed innovative products.

Founded in 2011, Hua signed an agreement with Roche in December 2011 to in-license its GKA program for treatment of type 2 diabetes. In March, the company completed its technology transfer with Roche and filed its clinical trial authorization in September. Shanghai FDA subsequently completed the site inspection and dossier review in just one month (*"China's Hua Medicine Licenses Worldwide Rights To Roche Diabetes Compound, More Deals On The Way" — PharmAsia News, Dec. 20, 2011 4:00 PM GMT*).

For Hua, the time was cut in half compared to the average 12-14 months to get from tech transfer to CTA and three to four months for site inspections.

The combination of Hua's collaborative R&D model, the efforts of its management team and partners, and support for innovation from China's State FDA culminated in the shortened filing time, Chen Li, founder and CEO of Hua Medicine, told *PharmAsia News*.

Chen has an intimate knowledge of the molecule because Roche developed the compound in its R&D center in Shanghai, when Chen was Roche's chief scientific officer. Chen was also one of the pioneers that helped establish Roche's R&D center in 2003; Roche was the first multinational pharmaceutical company to establish an R&D center in China (*"Roche China R&D Center Chief Scientific Officer Li Chen On Being a Pioneer in China: An Interview With PharmAsia News (Part 2 of 2)" — PharmAsia News, Aug. 26, 2009 9:58 AM GMT*).

The compound is treated as a locally developed innovative candidate, categorized as a Class I drug, according to Chen. A Class I drug, which is eligible for the agency's fast-track review policy, is defined by SFDA as a drug that has not been approved previously in another country.

"It usually takes five days for feedback from [Shanghai] FDA after filing a submission. In our case, we got feedback right on the next day of filing," Chen said.

According to China's drug approval process, provincial FDAs are responsible for site inspections and dossier reviews and SFDA/CDE will approve and conduct technical reviews.

It took only two weeks for Shanghai FDA to conduct the site inspection for Hua's seven research sites. Now, the drug is pending SFDA review; Chen expects to launch the Phase I trial for the compound by the middle of next year.

Developing innovative drugs for China represents a new step in China's evolution. For example, diabetes in China appears differently than in the West, with people developing the disease who are not obese, and so there is a need for drug development based on different ethnicity.

"We're working with medical clinics and hospitals and that's what the government wants to see, so that the new medicine we develop will be different when it reaches patients in China, instead of following on the existing trend of one size fits all," Chen said in an earlier interview (*"Meet China's New Innovators: Hua Medicine Looks To Take Flight With U.S. Venture Backing (Part 1)" — PharmAsia News, Sep. 19, 2011 2:00 PM GMT*).

Virtual Development Model

As one of China's emerging start-ups experimenting with innovative R&D models, Hua is managing its projects with a small internal management team and is leverag-

ing contract research organizations to advance its R&D projects. Hua is focusing on developing drugs for cancer, diabetes and CNS disorders.

In this case, Hua is partnering with several CROs, including **WuXi PharmaTech Inc., Hangzhou Tigermed Consulting Co., Ltd, Shanghai Center for Drug Metabolism and Pharmacokinetics Research, Asymchem Laboratories Inc.** and the **Chengdu Center for Drug Safety Evaluation**.

China CRO giant WuXi is also a Hua investor, and WuXi CEO Ge Li is a co-founder and sits on Hua's Board of Directors. Other investors include American venture capitalists, including Arch Venture Partners, Venrock and Fidelity Ventures, as well as Chinese VC Shanghai Alliance Investment Ltd.

Tigermed has also become a leading clinical CRO in China, and specializes in helping companies file applications for Class I drugs and manage clinical trials. Founded in 2002, Tigermed began its expansion in 2008 after an investment from Qiming Venture Partners. The company went public on the Shenzhen Stock Exchange in August and become the first CRO listed in mainland China (*"Tigermed To List In China At RMB 37.88" — PharmAsia News, Aug. 17, 2012 10:00 AM GMT*).

Another recent success story for Tigermed is **Beta Pharma Inc.**'s non-small cell lung cancer treatment *Conmana* (icotinib), an EGFR inhibitor that is a reformulation of **AstraZeneca PLC** 's *Iressa* (gefitinib) and Roche's *Tarceva* (erlotinib). Tigermed helped Beta Pharma manage clinical trials in China (*"Is Beta Pharma The Best Model For Innovation In China? Views From Lilly Asia Ventures And Other VCs" — PharmAsia News, Sep. 5, 2012 6:32 PM GMT*).

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