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Hua Medicine's Chen On Product Launch, Bayer Partnership And Reimbursement

CEO Talks On Strategy And Plans

by **Brian Yang**

Within a month of obtaining its global first approval in China, Hua Medicine's dorzagliatin is already available in hospitals. What was behind the successful launch of the first-in-class diabetes agent, what are reimbursement plans and how will local commercialization partner Bayer help? Founder and CEO Li Chen sits down to discuss these and other strategies.

[Hua Medicine \(Shanghai\) Ltd.](#) obtained the first approval globally for its novel diabetes drug Huatangning (dorzagliatin) in China last September and soon launched it to market.

Roughly eight months later, the Chinese company reported sales of the product - marketed by commercial partner [Bayer AG](#) in China - had reached CNY80m (\$11m), notable for an innovative new treatment not reimbursed by the country's public health insurance scheme and so paid for out-of-pocket by patients.

It had also entered a highly competitive sector dominated by multinationals such as [AstraZeneca PLC](#), [Merck & Co., Inc.](#), [Boehringer Ingelheim GmbH](#), [Sanofi](#) and [Novo Nordisk A/S](#).

Hua Medicine founder and CEO Li Chen tells *Scrip* in this audio interview that three major factors contributed to the successful domestic launch of the Chinese firm's novel oral antidiabetic dorzagliatin: actively engaging with contract manufacturers; in-China clinical development; and a recent regulatory rule that accelerated the roll-out.

China's diabetes market, the largest in the world in sufferer numbers, has seen rapid change.

While older drugs such as metformin are still widely prescribed, newer therapies including those that target GLP-1, DPP-4 and SGLT are all gaining market share.

However, the sector also has its own challenges, including a low (50%) diagnosis rate and of those diagnosed, only 50% are currently being treated. Unlike type 2 diabetes patients in the US, Chinese diabetics may be slightly overweight but are not usually obese and they report more glucose fluctuations, including post-prandial spikes.

Chen said differentiating factors for dorzagliatin as a first-in-class, oral glucokinase allosteric modulator include the fact it targets multiple metabolic mechanisms including pancreatic beta cell function, alpha cell glucose sensitivity and restoration of GLP-1 secretion.

The next step, he said, is to add metformin, DPP-1 and SGLT-1 drugs to target a broader patient population and develop an optimized second-generation version to address obesity in western patients.

Reimbursement Plans

To get quick reimbursement, Hua filed an application for the inclusion of dorzagliatin in China's National Reimbursement Drug List (NRDL) and has been given the okay for this.

However, getting approval is only the first step in a time-consuming process for listing. A drug must first enter the formularies of public hospitals in which 80% of drugs are sold in China, but in turn there are multiple constraints on that.

Chen acknowledged the challenges, but noted the Shanghai government has issued policies allowing new drugs to enter hospitals with no limits on product type or budget controls within three months after NRDL inclusion. A similar policy change is also taking place in Guangdong province.

Speaking on the Bayer partnership, Chen said Hua had received a CNY700m milestone payment and is slated to get another CNY800m from the German giant.

Falling At The Start Line: Chinese Firms Face Multiple Commercial Challenges Beyond Price, Coverage

By **Brian Yang**

30 May 2023

Sales of a global first-in-class dermatology drug that gained its first approval in China are falling well behind those of its overseas counterpart. In this case study, *Scrip* takes a deep dive into the multiple underlying factors determining success in the world's second-largest pharma market beyond pricing and reimbursement coverage, including complex hospital entry, dual channels and competition considerations.

[Read the full article here](#)

Time Stamps:

00-0005: Introduction to dorzagliatin

0005-0010: Factors behind the quick launch

0010-0015: Reimbursement, NRDL and challenges entering hospital formularies

0015-0020: Type 2 diabetes market in China

0020-0025: combination dosing, 2nd-gen dorzagliatin for overseas development

0025-0030: China's type 2 diabetes patient education

0030-0035: Bayer commercial partnership

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