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# Agenix seeks China SFDA nod for hepatitis candidate

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**Singapore:** Drug and diagnostic company Agenix announced that it was on track to submit a new drug clinical trial application with China's State Food and Drug Administration (SFDA) for its proprietary hepatitis B drug candidate, AGX-1009, to conduct clinical trials in patients with chronic hepatitis B who develop resistance to current approved therapies.

Agenix chairman and CEO, Mr Nick Weston, told the Australia-China Life Science Summit in Melbourne that, "Filing with SFDA will represent an important milestone for us and all other Australian companies active in China. As a clinical-stage drug and diagnostic development company, competition in patient recruitment, time, and costs can be challenging when advancing clinical programs. Agenix is successfully addressing these issues by working closely with our strategic partners in China via a unique joint Australian-China drug development model that will enable us to do the trials with much lower study costs and faster patient recruitment than is possible in developed markets."

The data we obtain may be used to support drug development in China and possibly other Asian markets as appropriate. We believe positive results from these efforts will add significant value to our patients, shareholders, as well as to the company," he said.

"Our local development activities in China demonstrate our commitment to develop a strong presence in the Chinese market, which has been projected to become the second largest pharmaceutical market in coming years. We are on track with our development plan and are grateful to our shareholders for their enthusiasm, patience, and long term support, "Mr Weston said.

Mr Weston added Agenix and its strategic partner, the Institute of Medicinal Biotechnology (IMB) of the Chinese Academy of Medical Sciences, were both confident the application would meet SFDA requirements. IMB is an internationally acknowledged leader in China's drug development and healthcare industry.

AGX-1009, is based on a proven active compound successfully used in Gilead's blockbuster Viread which is widely used in Europe and the US. It will be positioned as a low-cost, once-aday therapy for millions of chronic hepatitis B patients in China. AGX-1009 is patented at a chemical level in China to 2026 and international patent applications have been filed for its method of manufacture.

Mr Weston said IMB and Agenix were further encouraged by recently announced plans by China to support the development of innovative new drugs like AGX-1009.

"Some generic drugs will be given priority in the approval process, particularly drugs that are in short supply, lack a branded competitor or that are used to treat rare diseases. The recently announced plan allows producers of new drugs to provide a draft version of their application
when applying for registration and called for drug specifications to be clarified during the period between registration and mass production," he said.

China will spend US$1 trillion on healthcare in 2020 driven by a continuation of the nation's economic and demographic trends, healthcare reforms and policies laid out in the government's 12th Five-Year Development Plan (2011-2015).

"China's growing middle-class and an ageing population combined with government spending are all combining to boost demand and create highly positive market conditions and significant revenue-earning opportunities for established Australian businesses with a wholly owned China subsidiary as Agenix has through Agenix Biopharmaceutical Shanghai.