

## SFDA approves Sihuan diabetes drug trials

25 February 2013 | Regulatory | By BioSpectrum Bureau



**Singapore:** Sihuan Pharmaceutical's pinoxacin hydrochloride, a Category 1.1 new drug developed by the company's innovative drug R&D team, received approval for clinical studies from the State Food and Drug Administration (SFDA). Phase I of clinical studies are set to begin in the first half of this year. It is the fourth Category 1 innovative drug for which the company has received approval for clinical studies.

Pinoxacin hydrochloride is DPP-4 inhibitor class of oral hypoglycemic agents, a drug with a brand new structure for treating type II diabetes. It is clinically used to enhance the function of endogenous insulin for improving glycemic control, and long-term use can improve islet beta-cells function. Pre-clinical research has shown that DPP-4 inhibitors have potent in vitro and in vivo activities, a good selection profile, great stability and controllable quality, as well as better tolerance, with long-term administration showing a protective effect on pancreatic beta-cells.

In addition, the DPP-4 inhibitor will not cause serious side effects such as weight gain and hypoglycaemia seen in traditional diabetes drugs. Pinoxacin hydrochloride has good pharmacokinetic characteristics, high oral bioavailability, quick absorption, rapid onset and a longer duration. A once-daily dosage is expected to keep the patients' symptoms under control. The advantages of pinoxacin hydrochloride have proven the drug's growth potential present in the market.

According to statistics from IMS, in 2011, the diabetes drug market was one of the largest therapeutic areas in China. The dragon nation has an overall diabetes incidence rate of 9.7 percent, with the number of patients exceeding 100 million, making China the country with the largest number of diabetics in the world. Diabetes has also become the world's third largest therapeutic area after CCV diseases and tumor diseases, and therefore exhibits promising prospects.

Dr Che Fengsheng, chairman and CEO, Sihuan Pharmaceutical, said that, "Further to obtaining clinical approval for Benapenum, a class of new drug, in January, the company has again successfully obtained clinical approval for another new drug. This has proven the company's strengthened research and development capabilities and that its continuous investment has started to bear fruit. We believe pinoxacin hydrochloride will provide physicians and patients with better treatment options after its launch, and will mark an important milestone for Sihuan Pharmaceutical as it enters into another major therapeutic area. This will enable the company to further consolidate its diversified product lines while driving its sustainable growth."