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Sinhuan's generic heart drug gets production approval

01 November 2012 | News | By BioSpectrum Bureau

Singapore: Sihuan Pharmaceutical Holdings Group, a leading pharmaceutical company with the largest cardio-cerebral vascular (CCV) drug franchise in China's prescription market, announced that Roxatidine Acetate Hydrochloride for Injection (Roxatidine), Sihuan Pharmaceutical's first-to-market generic drug, received a new drug certificate and approval for production. The company plans to launch the drug to the market in or before the first quarter of next year.

Sihuan Pharmaceutical is the first pharmaceutical company to successfully register and develop Roxatidine in China, and has four years of administrative protection for the drug. Roxatidine is a fourth generation H2 receptor antagonist.

The drug is categorized into two formulations - oral and injectable. The oral form of the drug was first launched in Japan in 1986 and is mainly used for gastric and duodenal ulcers, zollinger-ellison syndrome, reflux esophagitis and gastritis. The injectable form of the drug, which debuted in Japan in 1995, is mainly used for gastrointestinal ulcers and bleeding and pre-anesthesia application.

It is one of the few drugs prescribed in hospitals to treat inpatients suffering from gastrointestinal bleeding. Currently, Roxatidine is widely used in various countries, including Korea, Germany, Italy, the Netherlands, Greece and South Africa.

Dr Che Fengsheng, chairman and CEO, Sihuan Pharmaceutical, said, "Leveraging our strong marketing capabilities and nationwide sales and distribution network, we believe that the official launch and manufacturing of Roxatidine will not only optimize our product mix, but will also strengthen our competitiveness and help us develop the market for therapeutic drugs for the digestive system. Looking forward, we will continue to invest in research and development in order to strengthen our leading position in the CCV drug market."