

China SFDA passes Sihuan Pharma's Roxatidine

28 May 2012 | News | By BioSpectrum Bureau

Sihuan's Roxatidine passes on-site inspection



Singapore: Sihuan Pharmaceutical Holdings' roxatidine acetate hydrochloride for injection (Roxatidine), which is the company's first-to-market generic drug, passed on-site inspection for drug registration conducted by the Chinese State Food and Drug Administration (SFDA). Sihuan Pharmaceutical, which is a leading pharmaceutical company with one-of-the largest cardio-cerebral vascular drug franchise (CCV) in China's prescription market, is expecting to obtain approval for production in the next three months.

The company plans to launch the drug to the market during the second half of the year, with hospitals as its major target market. It will be manufactured by Beijing Sihuan Pharmaceutical, a wholly-owned manufacturing subsidiary. Roxatidine is the 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 is mainly used for upper gastrointestinal bleeding and pre-anesthesia application. Currently, Roxatidine is widely used in various countries, including Korea, Germany, Italy, the Netherlands, Greece and South Africa.

Compared with other H₂ receptor antagonists, the Roxatidine contains higher selectivity for H₂ receptors and features a stronger effect on acid suppression. In addition, it contains a protective mucosal effect that other H₂ receptors do not have. Although Roxatidine has a similar therapeutic efficacy to proton pump inhibitors, it is safer, more stable and more cost-effective. These outstanding advantages are a testament to Roxatidine's clinical value. As a result, Roxatidine has been the first-line drug used for upper gastrointestinal bleeding in the overseas markets.

Gastrointestinal ulcers and bleeding is a common disease in China and has a significant patient base. With the fast-paced living environment, accelerated urbanization and the persistently high stress levels, the incidence rate of such diseases has been rising each year. Overall incidences of digestive diseases afflict 10-to-20 percent of the total population and have high recurrence rates. During the end of 2011, the size of the market reached \$3941.12 million (RMB\$25 billion), bringing promising market potential and prospects.

Dr Che Fengsheng, chairman and CEO, Sihuan Pharmaceutical, said that, "Capitalizing on the characteristics and advantages of Roxatidine, along with Sihuan Pharmaceutical's strong sales and marketing capabilities and nationwide sales network, we believe that this drug will bring its clinical therapeutic value into play with wide clinical use. Building on its leading position in the CCV drug market, Sihuan Pharmaceutical's launch of Roxatidine signifies Sihuan Pharmaceutical's foray into the digestive system therapeutic area. This strategic move is set to further promote the continued development and growth of Sihuan, thereby creating lucrative returns for the company and its shareholders."