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Sihuan gets SFDA nod for Nalmefene HCl

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Singapore: Sihuan Pharmaceutical's new category 3.1 drug, Nalmefene Hydrochloride Injection (Nalmefene Hydrochloride), received a new drug certificate (H20120078) and approval for production (2012S00818) from the Chinese State Food and Drug Administration (SFDA).

Nalmefene Hydrochloride is yet another generic drug for which the company has received approval for production following the Roxatidine Acetate Hydrochloridefor Injection. It will be manufactured by Beijing Sihuan Pharmaceutical, a wholly-owned manufacturing subsidiary of the Company.

Nalmefene hydrochloride is a next generation opioid (opium) receptor inhibitor following Naloxone and Naltrexone. The injection formulation of Naloxone hydrochloride was invented by Ohmeda Pharmaceuticals and was approved by the US FDA in 1995.

The clinical uses of Nalmefene hydrochloride include anti-shock, neuroprotection, treatment for acute morphine poisoning, drug relapse prevention, recovery from the after-effects of anesthesia such as respiratory and nerve center depression and the treatment of unconsciousness persons.

Dr Che Fengsheng, chairman and CEO, Sihuan Pharmaceutical, said, "Nalmefene Hydrochloride has shown unique characteristics for treatment and high clinical value. Its market demonstrates great potential to expand. We believe that our market share for Nalmefene Hydrochloride will see rapid growth, which will strengthen our position in drugs for the treatment of major diseases of the central nervous system. This will in turn enhance the continuous development and growth of Sihuan Pharmaceutical and create value for the shareholders and the company."