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TaiGen Biotechnology announces the submission of NDA for Taigexyn to the CFDA

31 May 2017 | News

Taigexyn is a novel broad spectrum antibiotic with excellent efficacy against drug-resistant bacteria available in both oral and intravenous formulations. The oral formulation is already approved for marketing and launched in Taiwan and mainland China.

TaiGen Biotechnology, a public listed company in Taipei Exchange and a leading research-based biotechnology company in Taiwan, has announced that it has submitted a New Drug Application (NDA) for the intravenous formulation of Taigexyn (Nemonoxacin) to the China Food and Drug Administration (CFDA).

Taigexyn is a novel broad spectrum antibiotic with excellent efficacy against drug-resistant bacteria available in both oral and intravenous formulations. The oral formulation is already approved for marketing and launched in Taiwan and mainland China. In addition, Taigexyn is also partnered in Russia, Commonwealth Independent States, Turkey, Mexico, Brazil and the Latin American territory for a total 32 countries worldwide.

The NDA submission is supported by a pivotal Phase 3 trial comparing intravenous formulations of Taigexyn 500 mg to levofloxacin 500 mg in 518 patients with moderate to severe community-acquired pneumonia. The clinical success rates were 91.8% for Taigexyn vs. 85.7% for levofloxacin and Taigexyn was shown to be non-inferior to levofloxacin meeting the primary endpoint of the pivotal trial.