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TaiGen gets TFDA nod for bacterial pneumonia drug

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Singapore: Taiwan based TaiGen Biotechnology has recieved Taiwan Food and Drug Administration (TFDA) approval for new drug application (NDA) of Taigexyn (nemonoxacin) oral formulation (500 mg) for the treatment of community-acquired bacterial pneumonia (CAP).

With this NDA approval, Taiwan is the first region to grant marketing approval to Taigexyn. An NDA for Taigexyn was also submitted to China FDA (CFDA) in April 2013 and is currently under review.

Taigexyn is a new chemical entity (NCE), broad spectrum, non-fluorinated quinolone antibiotic available in both oral and intravenous formulations. TaiGen have completed multi-national and multi-center clinical trials of Taigexyn in over 1280 subjects with demonstrated efficacy and safety. In the clinical trials conducted to this point, Taigexyn have shown activity against drug-resistant bacteria such as methicillin-resistant Staphylococcus aureus (MRSA) and quinolone-resistant MRSA as well as quinolone-resistant Streptococcus pneumoniae.

TaiGen owns the worldwide patent portfolio of Taigexyn that protects composition, use, and processes until 2029. The clinical development of the intravenous formulation in CAP is ongoing in Taiwan and mainland China.

Dr. Ming-Chu Hsu, Chairman and CEO of TaiGen said, "This is the first drug approval for TaiGen and we hope there are more to come. It proves that an NCE drug can be developed by a company in Taiwan and approved by the Taiwan regulatory authorities ahead of the rest of the world. This is a very important milestone for the TFDA and the entire Taiwan

pharmaceutical industry, especially for the future development of NCE drugs in Taiwan."

In June 2012, TaiGen out-licensed the exclusive rights of Taigexyn in mainland China to Zhejiang Medicine Co. and in January 2014, TaiGen out-licensed the exclusive rights in Russian Federation, Commonwealth Independent States, and Turkey to R-Pharm of Russia.