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ASIA EDITION

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Singapore: The China Food and Drug Administration (CFDA) has approved to market TaiGen Biotechnology's novel antibiotic, Taigexyn (nemonoxacin), in mainland China. TaiGen Biotechnology is a leading research-based and product-driven biotechnology company in Taiwan with a wholly-owned subsidiary in Beijing, China. The new antibiotic, Taigexyn (nemonoxacin) successfully cleared a Phase III trial late last year in Taiwan and mainland China to treat pneumonia.

Taigexyn is the first Class 1.1 new drug developed by a Taiwanese company to receive market approval in mainland China. It is also the first new drug approval after the CFDA announced the requirement of self-inspection of drug clinical trial data in July 2015. The drug is already approved in Taiwan.

Taigexyn is a non-fluorinated quinolone, broad spectrum antibiotic, with clinical trials demonstrating activity against drug-resistant bacteria such as methicillin-resistant Staphylococcus aureus (MRSA) and penicillin-resistant Streptococcus pneumonia (PRSP).

Taigexyn will be marketed in mainland China by Zhejiang Medicine Co through an exclusive marketing and manufacturing licensing agreement. TaiGen also partnered the exclusive rights in the Russian Federation, the Commonwealth of Independent States, and Turkey to R-Pharm of Russia.

"This is the second market approval for Taigexyn and will further expand its commercial opportunity," Ming-Chu Hsu, chairman and CEO of TaiGen said in a statement. "Mainland China is the largest antibiotic market in the world with annual

sales exceeding $12 billion. Taigexyn's excellent activity against drug-resistant bacteria and low propensity to resistance development is a valuable tool in fighting the problem of increasing antimicrobial resistance."

TaiGen has completed multi-national and multi-center clinical trials in community-acquired pneumonia (CAP) with demonstrated efficacy and safety. In particular, Taigexyn has clinical activity against drug-resistant bacteria such as methicillin-¬resistant Staphylococcus aureus (MRSA) and penicillin-resistant Streptococcus pneumonia (PRSP). Taigexyn, 250 mg capsules, has received marketing approval from Taiwan Food and Drug Administration and launched in theTaiwan market.

In addition to the oral formulation, TaiGen is planning to file for market approval of the intravenous formulation inChina in the second half of 2016. TaiGen owns the worldwide patent portfolio of Taigexyn that protects composition, use, and processes.

Taigexyn was granted both Qualified Infectious Disease Product (QIDP) and fast track designations by the US Food and Drug Administration for CAP and acute bacterial skin and skin structure infections (ABSSSI). These two designations will provide an additional five year extension to the NCE market exclusivity and priority review when applying for market approval in the US to TaiGen and/or its partners.