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TaiGen, Russian firm to co-develop antibiotic

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Singapore: Taiwan based TaiGen Biotechnology has collaborated with R-Pharm, a Russian pharmaceutical company, to develop and commercialize nemonoxacin (Taigexyn) in the Russian Federation, Turkey and other members of the Commonwealth Independent States (CIS).

Nemonoxacin is a novel antibiotic for the treatment of bacterial infections including those caused by drug-resistant bacteria.

Under the terms of the agreement, R-Pharm will be responsible for the development, registration and commercialization of nemonoxacin in these territories and assume all associated costs. In exchange for the exclusive rights, TaiGen will receive an upfront payment and is eligible for additional regulatory and commercial milestones as well as royalties on product sales in the future.

Nemonoxacin is a novel non-fluorinated quinolone available in both oral and intravenous formulations. In the clinical trials conducted to this point, nemonoxacin has 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 has completed a multi-center Phase 2 and 3 of the oral formulation in community-acquired pneumonia (CAP) in Taiwan and mainland China and submitted NDA to regulatory authorities in both countries in 2013.

In June 2012, TaiGen out-licensed the exclusive rights of mainland China to Zhejiang Medicine. In the U.S., TaiGen has completed two Phase 2 studies, one in CAP and the other in diabetic foot infections (DFI).

In December 2013, the U.S. FDA granted nemonoxacin Qualified Infectious Disease Product (QIDP) and Fast Track designations for CAP and acute bacterial skin and skin structure infections (ABSSSI). TaiGen owns the worldwide patent portfolio of nemonoxacin that protects composition, use, and processes until 2029.

"We are very excited about the opportunity to bring this truly innovative anti-infective compound to patients in Russia, other former Soviet Union states, and Turkey and will use our clinical, regulatory and commercial capabilities to ensure speedy

registration and successful launch," said Mr Vasily G. Ignatiev, CEO, R-Pharm.

Dr Ming-Chu Hsu, President and Chief Executive Officer of TaiGen, said, "We are very impressed with the R-Pharm's experience and their commitment to infectious diseases. The Russian Federation and Turkey are among the world's top twenty pharmaceutical markets and their growth in the next five years will outpace the U.S., EU and Japan, according to IMS.

Both countries also have a very high incidence of drug-resistance bacterial infections.Together we can bring innovative medicines such as nemonoxacin to these areas where the medical need is very high."