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TaiGen files NDA for Nemonoxacin in Taiwan, China

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Singapore: Taiwan's TaiGen Biotechnology has submitted New Drug Application (NDA) for the oral formulation of nemonoxacin with the Taiwan Food and Drug Administration (TFDA) and China's Food and Drug Administration (SFDA).

Approval is expected in the first half of 2014. Nemonoxacin is the first pharmaceutical product to fall under the Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs of the Economic Cooperation Framework Agreement (ECFA) between Taiwan and mainland China.

It is also the first new drug from Taiwan to meet the requirements of CFDA's Category 1.1 New Drug. Drugs under this classification have to be new chemical entities (NCEs) that have not been marketed in any country in the world. Nemonoxacin, thus, represents a landmark in the continued development of cross-strait relationship between the pharmaceutical industry and regulatory agencies.

Nemonoxacin is a NCE, broad spectrum antibiotic with excellent efficacy and safety profile. The NDA submission for nemonoxacin is supported by a pivotal phase III trial with 532 patients in community-acquired pneumonia (CAP). The trial was conducted in both Taiwan and mainland China (441 patients from mainland China and 91 patients from Taiwan) that met all primary and secondary endpoints including non-inferiority to the comparator, levofloxacin.

Dr Ming-Chu Hsu, president and CEO, TaiGen, said that, "Not only nemonoxacin is our first product to the market, it is also an indication that a world class medicine can be discovered and developed in Taiwan. TaiGen is well positioned to advance in the world's fastest pharmaceutical market, mainland China."