

Pharmigene leads in adverse drug reaction tests

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Treatment of Pompe disease, an inherited disorder caused by build-up of a complex sugar called glycogen in the body's cells, was unknown to the scientific fraternity until Dr Y T Chen discovered the only life-saving treatment. Dr Chen, a professor at Duke University Medical Center and Academia Sinica in Taiwan, and his team found that patients with specific genotypes are more susceptible to the fatal Stevens Johnson syndrome (SJS)/ Toxic Epidermal Necrolysis (TEN) as compared to the general population.

The breakthrough discovery by Dr Chen attracted healthcare experts and venture capitalists and this led to the establishment of Pharmigene in 2005. The company, which aims to popularize and commercialize Dr Chen's discoveries in order to save human lives, won the BioSpectrum Asia Pacific Bioscience Industry Emerging Company of the Year for 2011.

Pharmigene, now striding under the guidance of CEO Dr Luke Chen, possesses patents in key regions, such as the US, Europe and China. Dr Luke Chen has years of leadership experience in marketing, sales, business development, product development, manufacturing, licensing and has held partnerships with companies, including Agilent Technologies, Hewlett Packard, Incyte, Clontech and Scimagix.

Pharmigene has obtained ISO 13485/9001 and GMP certifications and is manufacturing its DNA genetic tests under the most stringent guidelines. It has validated the tests with clinical studies that involved thousands of patients. Pharmigene's tests have earned the CE Mark and have obtained IVD clearance from the Department of Health in Taiwan.

Pharmigene's HLA-B* 1502 Assessment Test was selected as the key screening test for a clinical prospective study that involved 27 hospitals and 4,500 patients. It has also received patent "Risk Assessment for Adverse Drug Reactions" in Singapore and has secured patents related to genetic-based methods to fight SJS and TENS in the key global regions.

Dr Luke Chen, while talking about the various hurdles faced by the company, says, "The greatest challenges have been obtaining the necessary regulatory approvals in the countries where we provide our test kits. Since our technologies are associated with adverse drug reactions (ADR) induced by several popular but inexpensive generic drugs, it is difficult in concept to prescribe a costlier companion diagnostic test with these generic drugs."

Diagnostic test leaders, including Quest Diagnostics, Lab Corp, Arup Consult and medical centers such as Mayo Clinic and UCLA, have begun screening patients for HLA-B*1502 prior to prescribing carbamazepine and phenytoin in prevention of SJS/TEN. Over 50 hospitals and diagnostic testing centers in Taiwan, Thailand, Indonesia, and the Philippines have also started to screen patients for HLA-B*1502 prior to prescribing the drugs. In 2011, Pharmigene intends to expand its reach into key regions such as Europe, China, India and Japan among other countries.

On receiving the BioSpectrum Asia Pacific Emerging Company of the Year Award for 2011, Dr Luke Chen says, "We at Pharmigene are honored to accept this award and to be recognized for our efforts in bettering the world by helping healthcare providers and patients making better informed decisions about their care. We are proud to receive the recognition from BioSpectrum and will continue to work to improve the world of personalized medicine."