

A PIONEER IN DRUG INNOVATION

A Chinese biotech enterprise is **SWIMMING AGAINST THE FLOW** by developing new drugs



A small-molecule drug for treating peripheral T-cell lymphoma (PTCL), chidamide is the first drug of its kind developed from start to finish in China. It hit the market in early 2015, the crowning achievement of 14 years of effort by researchers at Shenzhen's Chipscreen Biosciences.

Chipscreen Biosciences is a biotech enterprise founded by a team of entrepreneurs with extensive research and management experience in the US. When the company's CEO, Dr. Lu Xianping, left his established career at a US pharmaceutical company in 2001 to establish Chipscreen in Shenzhen, China, many Chinese

pharmaceutical companies were busy imitating existing drugs or making generic ones. Since developing a new drug can cost billions of dollars and take more than 10 years, the risk is high, especially for small start-ups.

But Lu was not content with imitation. He wanted to focus on scientific exploration and believed that small start-ups have an edge in breakthrough innovation. Lu's confidence lay in an integrated technical system for drug discovery that he and his colleagues developed based on chemical genomics. Using active compounds as probes to characterize proteome functions, this novel approach

allows small molecules to be systematically screened as new therapeutic targets, enhancing the ability to create target-specific chemical drugs. "This technology guides our target study and early evaluation," says Lu. "It allows us to more efficiently assess the usefulness of molecules we created early on and their potential development risk."

The chemical genomics approach led to the discovery of chidamide, a highly selective histone deacetylase (HDAC) inhibitor. Having worked on HDAC since 2001, Lu and his colleagues found that chidamide inhibits certain HDAC subtypes and achieves an anti-tumour effect by changing gene expression in multiple signal pathways and inducing tumour differentiation. Their phase I clinical trial was with solid tumours, but results showed that chidamide was more effective against PTCL, a rare lymph-node cancer.

Chidamide has benefited PTCL patients in China, who now have access to a safe and highly effective treatment at much lower cost. "Meeting such originally unmet clinical needs is ultimately what motivated us to return and found Chipscreen," says Lu. He is confident that the application of chidamide to other diseases such as breast cancer will yield further social and economic benefits.

The approval of chidamide also broke China's reliance on foreign imports for innovative drugs. The out-licensing of its overseas patents brought Chipscreen huge milestone payments and made chidamide the first original Chinese drug authorized for use in the US and other developed countries. This sets a precedent for China to change from a drug imitator to a creator.

Chipscreen's success is attributable to a strong R&D team, which harnessed expertise in biochemistry, molecular medicine, bioinformatics, immunology, tumours, endocrinology and metabolism. Many of its team members have PhDs, and some have overseas degrees. "We were attracted by the massive market opportunity here in China," said Lu. "Shenzhen is a vibrant city with a strong entrepreneurial atmosphere and a friendly immigrant culture. Its policies are pro-business and supportive to the biomedical industry."

The company has grown from around 50 employees 10 years ago to 300 today. With an integrated technical and management team, Chipscreen has developed the capacity to engage in the entire drug industrialization process. It has several new drug projects in the pipeline, primarily targeting malignant tumours, diabetes and autoimmune diseases. A new compound for treating type II diabetes, chigitazar, is finishing phase III clinical trials and is expected to hit the market in 2018. Phase II clinical trials are planned for a novel multi-pathway inhibitor for cancer, CS2164, the first of its kind in the world.

Chipscreen is currently building a new R&D centre and manufacturing base in Chengdu, Western China, and basic science researchers, technicians and good drug analysts are needed for it, says Lu. ■



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