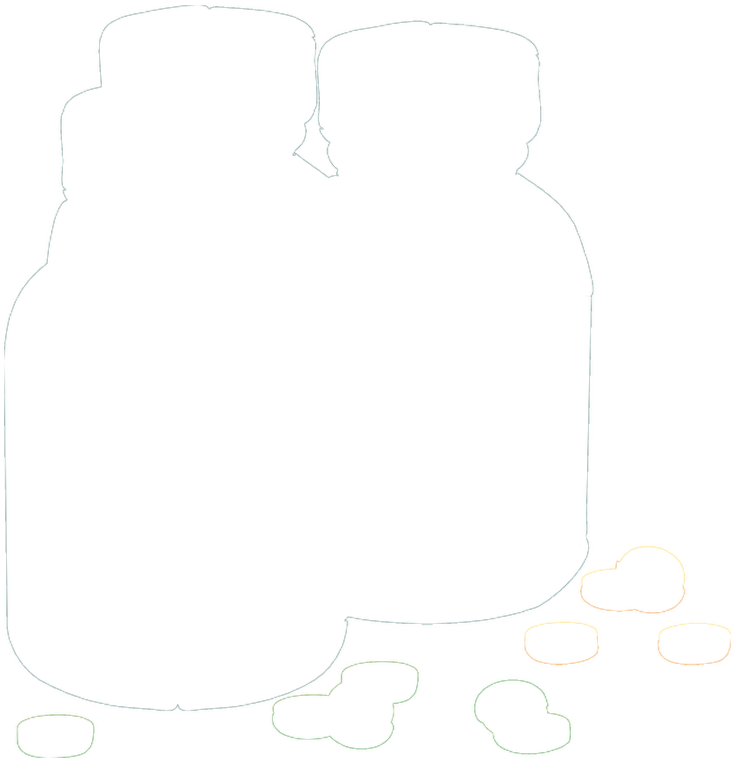
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

CFDA approves peripheral T-cell lymphoma drug

12 January 2015 | Regulatory | By BioSpectrum Bureau

CFDA approves peripheral T-cell lymphoma drug



â€Ž**Singapore:** Chinese Food and Drug Administration (CFDA) has approved Chidamide (Epidaza), an orally administrated and subtype-selective histone deacetylase (HDAC) inhibitor for relapsed or refractory peripheral T-cell lymphoma (PTCL) patients.

Developed by Chipscreen Biosciences, a China based biotech company, Chidamide is an orally bioavailable, low-nanomolar inhibitor of cancer-associated histone deacetylase (HDAC) enzymes with favorable pharmacology and tolerability profiles relative to existing benzamide and non-benzamide HDAC inhibitors. It targets specifically the subtype 1, 2, 3 of Class I and subtype 10 of Class IIb HDAC and is being studied in multiple clinical trials as a single agent or in combination with chemotherapeutic agents for the treatment of various hematological and solid cancers.

Peripheral T-cell lymphomas (PTCL) is a set of rare and heterogeneous group of mature T- and natural killer (NK)-cell neoplasms associated with poor outcome. PTCL makes up 25 percent to 30 percent of all Non-Hodgkin's lymphoma (NHL) cases in China, much higher than that seen in Western countries of 10 percent to 15 percent.

"Chidamide is the first new molecular entity discovered and developed by Chipscreen scientists in China. The CFDA's decision to approval the world first orally administrated selective HDACi for PTCLs is an important validation of the drug's therapeutic potential for this urgent medical need for Chinese PTCLs patients. The orally administrated Chidamide not just will provide affordable innovative treatment for the Chinese patients whom otherwise have no option to obtain most up-to-

dated new treatment beyond conventional chemotherapies, but also have great potential, based on its unique epigenetic mechanism of actions and existing knowledge from the field, to be easily combined with other treatment modalities in comprehensive control and management of cancer patients in fight against drug resistance and tumor recurrence," said Mr Xian-Ping LU, chief executive officer and chief scientific officer, Chipscreen Biosciences.