BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

GNT Biotech, TPSC ink deal for anticancer drug Chidamide

22 June 2018 | News

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Taiwan's GNT Biotech & Medicals recently announced that it has granted exclusive sales and marketing rights of anticancer drug Chidamide to pharmaceutical distribution company Taiwan Specialty Pharma Corp. (TSPC) for two indications; hormone receptor-positive, HER-2 negative late stage breast cancer in post-menopausal patients; and peripheral T-cell lymphoma (PTCL) in Taiwan.

The licensing agreement includes upfront and milestone payments of up to NT$30 million (approx $1million), with royalties from sales to be awarded separately.

GNTbm also announced that it had already begun its Phase III clinical trial for Chidamide when administered together with exemestane (Aromasin), an aromatase inhibitor, for the treatment of late stage breast cancer after receiving approval in 2017 for the trial by the Taiwan Food and Drug Administration (TFDA). The trial in six medical centers in Taiwan is being conducted in collaboration with Chipscreen Biosciences Ltd., of Shenzhen, China, using the same clinical trial protocol as its Phase III trial for the same drug combination in China.

Chidamide, a new generation of epigenetic regulator and subtype-selective HDAC inhibitor, was originally developed by Chipscreen Biosciences in 2003.

The first approved indication of Chidamide was the rare disease refractory/recurrent peripheral T-cell lymphoma. Chipscreen Biosciences received China FDA (CFDA) approval for treatment of this condition in China in December 2014.To date, more than 4,000 patients with PTCL have been treated with Chidamide.

GNTbm is expected to submit an NDA to the TFDA for PTCL in 2019, and hopes to receive market approval sometime in 2020. The second indication for Chidamide is in combination with Aromasin for the treatment of hormone receptor-positive, HER-2 negative late stage breast cancer in post-menopausal patients.

Dr. Chia-Nan (Alex) Chen, Chairman of GNTbm, stated that GNTbm had in-licensed Chidamide with the intent to invest in the development of new indications through locally-conducted clinical trials, and also intend to produce the API for this drug

locally. The company will invest large sums of money and manpower to do so, he said.

"We will partner with local drug companies Formosa Laboratories and Sinphar Pharmaceutical to manufacture the API and for formulation, respectively," said Chen.

"We are very pleased to choose Taiwan Specialty Pharma Corp. (TSPC) as our sales partner inTaiwan. TSPC has many years of experience in pharmaceutical sales and marketing, especially in treatments for rare diseases, and in particular blood cancer. GNTbm and TSPC are very optimistic about the sale of Chidamide for peripheral T-cell lymphoma and advanced breast cancer patients in Taiwan," added Chen.