BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

China approves first hormone replacement therapy for hypoparathyroidism

June 4, 2021 | News

VISEN Pharmaceuticals obtains IND approval for Phase III clinical trial



On account of World Hypopara Awareness Day on June 1st, VISEN Pharmaceuticals, a biotech company focused on developing and commercializing innovative endocrine drugs, announced that it has obtained the investigational new drug (IND) approval from the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) for the phase III China clinical trial (PaTHway China Trial) of TransCon™ parathyroid hormone on June 1 and will soon initiate the study of TransCon™ PTH in patients with hypoparathyroidism (HP) in China.

PaTHway China Trial is a randomized, double-blind, placebo-controlled, parallel, multi-center phase III study to assess the potential of TransCon™ PTH as a hormone replacement therapy. The study aims to enable patients to have serum calcium (sCa) within the normal range and, in the meanwhile, independent from usual care.

The key secondary efficacy endpoints in PaTHway China include changes in the scores in the Hypoparathyroidism Patient Experience Scale (HPES) and 36 Item Short Form Health Survey (SF-36) reported by HP patients receiving TransCon™ PTH.

Dr. Jun Yang, CMO of VISEN Pharmaceuticals, said, "Hormone replacement has always been the primary treatment option for hormonal deficiency states. However, no effective parathyroid replacement therapy is available for hypoparathyroidism to correct related pathophysiological changes and metabolic disorders. TransCon™ PTH is an investigational, innovative, long-acting prodrug of PTH. It is being developed as a once-daily hormone replacement therapy for adults with HP, designed to replace PTH at physiologic levels for 24 hours every day, and address both short-term symptoms and long-term complications of the disease. It is very encouraging to obtain the IND approval for Phase III clinical trial in China on the World Hypopara Awareness Day, which will inspire us to work hard to accelerate the development of innovative drugs and address unmet clinical needs!"