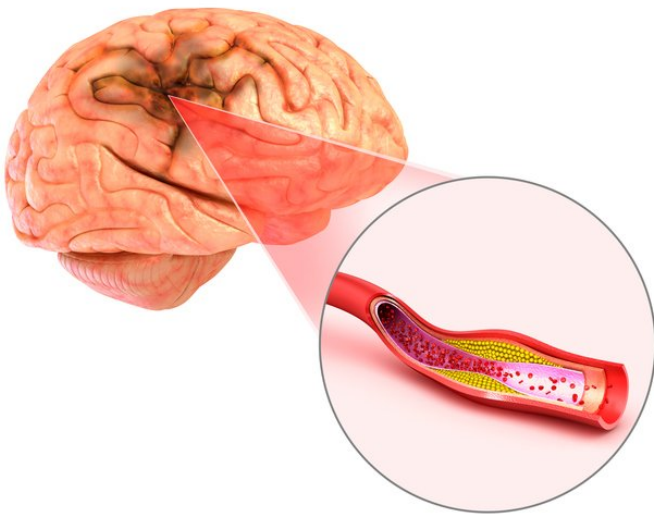


Clinical trials verification of "Cinepazide Maleate Injection (Kelinao)" completed to treat Acute Ischemic Stroke

03 June 2019 | News

Product has obtained post-launch verification promising prognosis of stroke patients, lower disability rate and improve cerebral circulation



Sihuan Pharmaceutical Group Ltd, the largest cardio-cerebral vascular (CCV) drug manufacturer in China's prescription drug market announced the completion of post-launch clinical trials of "Cinepazide Maleate Injection (Kelinao)" for the treatment of acute ischemic stroke. By this, the product has obtained post-launch large clinical trials verification, demonstrating improvement in the prognosis of stroke patients, lower disability rate and improve cerebral circulation for stroke patients.

The Group responded proactively to the injection re-evaluation requirement of the China Food and Drug Administration (CFDA) and commenced post-launch large clinical trials verification in 2016. The Studies took three years to complete and the Group has invested nearly RMB100 million on the Studies and successfully completed the supplementary application prior to the specified time limit, ensuring continuous product availability and persistent treatment to the patient.

Prof Cui Liying, committee Chairman of the neurology branch in Chinese Medical Association who also serves at the department of neurology in Peking Union Medical College Hospital lead the study. Studies involved multiple hospitals nationwide. A high standard evidence-based research was designed as a randomized, double-blinded and randomized control trial (RCT) clinical trial, aiming at evaluating the efficacy and safety of the Product for the treatment of acute ischemic stroke. A total of 1,301 patients (aged 18 to 80) suffering from moderate to severe acute ischemic stroke with acute onset within 48 hours have been enrolled in the Studies. The subjects were arranged to receive a 14-day study medication therapy and to complete a follow-up visit and evaluation on the 90th day thereafter. Results of the Studies showed that the Product is effective in promoting the functional recovery after 90 days in stroke patients. Cinepazide Maleate group significantly outperformed the control group in terms of mRS on the 90th day of the primary efficacy endpoint. The endpoint reflects a patient's disability and prognosis and is the globally common-used standard in assessing the prognosis of stroke patients. The results suggested that the Product significantly decreases disability rate with no new adverse events.

Dr Che Fengsheng, Chairman and CEO of Sihuan Pharmaceutical, said, "The Studies verified the efficacy and safety of the Product for the treatment of acute ischemic stroke through scientific design and strict management. The Product will also reshape the landscape for stroke treatment while benefiting more patients, families and society with its proven therapeutic efficacy."