EXPANDED ACCESS POLICY OF SANBEXIN SUBLINGUAL TABLETS IN THE US

Simcere is a biopharmaceutical company committed to the development of safe and effective novel therapies. Simcere is developing Sanbexin Sublingual Tablets (Sanbexin SL) for use in the treatment of acute ischemic stroke in adults.

In August 2024, The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to Sanbexin SL for use in the treatment of acute ischemic stroke in adults.

Expanded Access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational drug for treatment outside of a clinical trial when no comparable or satisfactory alternative therapy exists.

As a general policy, Simcere will not provide Sanbexin SL on Expanded Access at this time anywhere in the world. Simcere believes that participation in our clinical trial program is the most appropriate way to access our investigational therapy. Simcere will continue to assess the eligibility requirements and criteria for Early Access and will re-evaluate this policy from time to time.