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ASIA EDITION

Beike awaits CFDA nod for stem cell application

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Singapore: China-based Beike Biotechnology has recieved Chinese Food and Drug Administration (CFDA) nod for filing the approval application for human umbilical cord (UC) derived mesenchymal stem cells (MSCs) for clinical translation and treatment of Systemic Lupus Erythamatosus (SLE).

Beike submitted the investigational new drug (NID) application to register their UC MSCs for clinical use to the Guangdong Province Food and Drug Administration on October 17th, 2013.

Post approval, Guangdong Food and Drug Administration (Guangdong FDA) carried on-site inspections for Beike's Shenzhen research sites as well as entrusted research facilities in Guangzhou, Beijing, and Shanghai for three months. The administration also evaluated the registered testing samples to inspect authenticity of Beike's research work. With joint efforts from all members in the project group, Beike's four research sites above all passed the inspection of the Guangdong FDA smoothly.

After being inspected by the Guangdong FDA, testing samples were delivered to National Institutes for Food and Drug Control for registration tests in early March, 2014. After qualification, NID application for registration of Beike Biotechnology's stem cells officially entered the Drug Review Center in China's Drug and Food Administration queue for review.

Dr Sean Hu, chairman and founder, Beike commented, "Beike's research and safety accreditation is well documented. However without government approval it doesn't mean much to the public who is need of this technology. While only in the application process, it is a critical step forward towards the regulation and control of stem cell technology in order to provide

safe and ethical medical options to the world. Cooperation is vital in today's ever-changing technological world, and Beike Biotech hopes that more companies and governments will move in the same direction of regulation and approval."