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Singapore: Taiwan-based ScinoPharm and China-based Nanjing King-friend Biochemical Pharmaceutical have entered into a collaboration for joint research and development of Regadenoson for China market.

Regadenoson is a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undertake adequate exercise stress. As Regadenoson dosing is not dependent on patient weight or renal impairment and can be administered by rapid injection.

ScinoPharm will be responsible for the development and manufacturing of the Active Pharmaceutical Ingredient (API) for Regadenoson. Both sides will jointly develop the injection technology and conduct clinical trials. NKF will take charge of the actual sterile injection production and drug certificate applications with the China Food and Drug Administration. The application for approval of human clinical trials in China is expected in late 2015 and the drug products are to be commercialized by 2020 there. Both parties will share the profits after launch. Regadenoson was approved for sale in the United States in 2008, but its drug license has not yet been applied for in China. Hence, as per the classification of chemical drug registration in China, Regadenoson requires human pharmacokinetic studies and at least 100 pairs of randomized and controlled clinical trials.

"ScinoPharm is pleased to become a strategic partner of NKF in order to advance the company's original expertise in generic API's further into the development of new drugs, thus enhancing the company's market value and long-term competitiveness. This is ScinoPharm's first new drug development project in Chinese market, thus furthering the implementation of the company's strategy to become a fully integrated pharmaceutical company," said Dr Chen Yung Fa, CEO, ScinoPharm.

In 2013, Regadenoson's global sales amounted to about USD530 million. Sales in China are expected to reach $35-50 million after the product becomes commercially available in the market.

Nanjing King-friend Biochemical Pharmaceutical's manufacturing facility has compliance nod from China, United States, European Union (EU), Japan, and Germany. The company has also engaged in long-term cooperation with several of the top 500 global pharmaceutical companies, involving the production of heparin sodium and a low molecular weight heparin product.