

May 10, 2019

Notification of a Contract Concluded for Tadalafil, a Phosphodiesterase-5 Inhibitor

Nippon Shinyaku Co., Ltd. (Head office, Kyoto City; President, Shigenobu Maekawa; hereinafter Nippon Shinyaku), Eli Lilly Japan K.K. (Head office, Kobe City; Representative Director and President, Patrik Jonsson; hereinafter Eli Lilly Japan), and Eli Lilly and Company (Head office, Indianapolis, Indiana, USA; Chairman and Chief Executive Officer, David A. Ricks; hereinafter Lilly) concluded a contract for transferring marketing authorization in Japan for tadalafil products (Cialis[®] tablet, Adcirca[®] tablet, and Zalutia[®] tablet).

Under the contract, Nippon Shinyaku will be the marketing authorization holder of tadalafil products in Japan in the first quarter of 2020.

Tadalafil was first introduced into Japan in July 2007 when Eli Lilly Japan received regulatory approval of Cialis tablet, a treatment for erectile dysfunction, which was launched in September 2007. In July 2009, Eli Lilly Japan and Nippon Shinyaku concluded a tadalafil promotion agreement, which defined the current role of Eli Lilly Japan as market authorization holder, and Nippon Shinyaku as sales distributor within the country. We have been providing new treatment options for patients suffering from diseases such as pulmonary arterial hypertension and dysuria associated with benign prostatic hyperplasia through providing Adcirca tablet in December 2009, and Zalutia tablet in April 2014, respectively.

Nippon Shinyaku will continue to provide information to promote the proper use of tadalafil products.

About Nippon Shinyaku

Our mission is to help people lead healthier and happier lives. Through creating unique medicines that will bring hope to patients and families struggling with illness, we aim to be an organization trusted by the community. We are most focusing on the therapeutic areas of Urology and pulmonary arterial hypertension and tadalafil products meet the areas. We would like to contribute communities through proper medical information. Please visit our website (<http://www.nippon-shinyaku.co.jp/english/>) for products or detailed information.