

Kyowa Hakko Kirin Announces the Intent to File Istradefylline (KW-6002) for Parkinson's Disease with the US FDA

Tokyo, Japan, October 17th, 2017 -- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") today announced that it has started to prepare for filing a new drug application (NDA) Complete Response Resubmission to the U.S. Food and Drug Administration (FDA) for istradefylline (Code No.: KW-6002) based on the feedback from the FDA and the result of clinical studies separately conducted in the US and Europe, and Japan. Expected timing of the resubmission will be in 2018.

The Kyowa Hakko Kirin Group strives to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

About istradefylline (KW-6002)

Istradefylline is an adenosine A_{2A} receptor antagonist and discovered by Kyowa Hakko Kirin. Adenosine A_{2A} receptors are G protein-coupled receptor (GPCR), and also one of the receptors of adenosine, a substance widely distributed in the human body. In the brain, adenosine A_{2A} receptors are considered to be present specifically in the basal ganglia, of which degeneration or abnormality is noted in Parkinson's disease. The basal ganglia are known to play an important role in motor control. In Japan, Kyowa Hakko Kirin has marketed istradefylline as the brand name NOURIAST® since May, 2013.