

**FOR IMMEDIATE RELEASE**

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**Kyowa Hakko Kirin Initiates a Global Phase 3 Trial of Istradefylline (KW-6002) for Parkinson’s Disease**

Tokyo, Japan, November 21, 2013 --- Kyowa Hakko Kirin Co., Ltd. (Tokyo: 4151, President and CEO: Nobuo Hanai, "Kyowa Hakko Kirin") today announced the initiation of a global phase 3 clinical trial of istradefylline (generic name / code name: KW-6002), for Parkinson’s disease. This global clinical trial is being conducted under a Special Protocol Assessment (SPA) agreement with the US Food and Drug Administration.

Istradefylline is a first-in-class adenosine A<sub>2A</sub> receptor antagonist antiparkinsonian agent and has been marketed as the brand name NOURIAST<sup>®</sup> in Japan since May 30, 2013.

Kyowa Hakko Kirin has four strategic categories including the central nervous system (CNS) area, and will contribute to the treatment of patients suffering from Parkinson’s disease and other CNS diseases.

Outline of the Global Phase 3 Trial

ClinicalTrials.gov Identifier	NCT01968031
Design	Double-blind, placebo-controlled, randomized, multinational, multicenter phase 3 study
Subjects	609 moderate to severe Parkinson’s disease patients with wearing-off phenomena on levodopa therapy
Number of Sites	95 sites in eight countries
Doses and Treatment Duration	20 mg, 40 mg of istradefylline or placebo, orally once daily for 12 weeks
Primary Endpoint	Change from baseline in OFF hours per day

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**About Adenosine A<sub>2A</sub> receptor**

Adenosine A<sub>2A</sub> receptors are a 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<sub>2A</sub> 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.

**About Parkinson's disease**

A progressive, neurodegenerative disease characterized by motor symptoms such as tremors, rigidity, slow movement and postural reflex disorders. It is thought to be caused by progressive degeneration associated with decreased levels of dopamine in certain parts of the brain, i.e., the substantia nigra and striatum.

**About Four categories**

These are the following four disease areas: Nephrology, Oncology, Immunology&Allergy, and Central Nervous System, as presented in Kyowa Hakko Kirin's FY 2013-2015 medium-term business plan.