

## **FOR IMMEDIATE RELEASE**

Listed Company Name: Kyowa Hakko Kirin Co., Ltd.

Representative: Nobuo Hanai, President and CEO

(Code no.: 4151, First Section of Tokyo)

Inquiries: Shigeru Morotomi, Managing Officer

Corporate Communications Department

Telephone: +81-3-3282-0009

## **Approval for manufacturing and marketing of NOURIAST<sup>®</sup> tablets 20 mg, a novel antiparkinsonian agent**

Tokyo, Japan, March 25, 2013 — Kyowa Hakko Kirin Co., Ltd. (President and CEO: Nobuo Hanai; “Kyowa Hakko Kirin”), announced today that NOURIAST<sup>®</sup> tablets 20 mg (nonproprietary name: istradefylline; referred to below as “NOURIAST<sup>®</sup>”), a novel antiparkinsonian agent, has been approved for manufacturing and marketing in Japan.

NOURIAST<sup>®</sup> is a selective adenosine A<sub>2A</sub> receptor<sup>1</sup> antagonist for Parkinson’s disease<sup>2</sup> of which action site is clearly distinct from the existing agents acting on dopamine receptors or dopamine metabolism. In clinical trials in Japan, NOURIAST<sup>®</sup> improved wearing-off phenomena and was well tolerated in Parkinson’s disease patients treated with levodopa<sup>3</sup>. Based on the clinical outcomes, Kyowa Hakko Kirin submitted an application for manufacturing and marketing approval on March 30, 2012. NOURIAST<sup>®</sup> is authorized as the world’s first antiparkinsonian agent of a first-in-class adenosine A<sub>2A</sub> receptor antagonist.

Kyowa Hakko Kirin has four strategic categories<sup>4</sup> including the central nervous system (CNS) area, and will contribute to the treatment of patients suffering from Parkinson’s disease and other CNS diseases.

\*\*\*ENDS\*\*\*

- 1: **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.
  
- 2: **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. The number of patients in Japan is estimated to be 150,000 to 200,000.
  
- 3: **Levodopa:** Since dopamine deficiency causes Parkinson's disease, the symptoms can be improved by increasing dopamine levels in the brain. However, because dopamine cannot cross the blood-brain barrier, levodopa (L-dopa), which does cross the blood-brain barrier, is administered instead. Levodopa converts to dopamine in the brain, resulting in improving the dopamine deficiency.
  
- 4: **Four categories:** These are the following four disease areas: Nephrology, Oncology, Immunology, and Central Nervous System, as presented in Kyowa Hakko Kirin's FY 2013-2015 medium-term business plan.

### **Product summary for NOURIAST<sup>®</sup>**

Brand name	NOURIAST <sup>®</sup> tablets 20 mg
Nonproprietary name	Istradefylline
Indications	Improvement of wearing-off phenomena in patients with Parkinson's disease on concomitant treatment with levodopa-containing products
Dosage and administration	To be administered concomitantly with levodopa-containing products. The usual adult dosage of istradefylline is 20 mg orally administered once daily. According to symptoms, 40 mg of istradefylline can be orally administered once daily.
Date of approval	March 25, 2013