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adults with Parkinson's  
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## Istradefylline: A new add-on drug to treat off episodes in adults with Parkinson's disease

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### ABSTRACT

The U.S. Food and Drug Administration on 27/08/2019 approved Istradefylline tablets as an add-on treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes. An "off" episode is a time when a patient's medications are not working well, causing an increase in Parkinson's disease symptoms, such as tremor and difficulty walking.

**Keywords:** Istradefylline, Parkinson's disease, off episodes, wearing off phenomenon, dyskinesia

### Parkinson's Disease (PD)

Parkinson's disease is a debilitating condition that profoundly impacts patients' lives. According to the National Institutes of Health, PD is the second-most common neurodegenerative disorder in the U.S. after Alzheimer's disease. An estimated 50,000 Americans are diagnosed with PD each year, and about one million Americans have the condition. The neurological disorder typically occurs in people over age 60, although it can occur earlier. It happens when cells in the brain, which produce a chemical called dopamine, become impaired or die. Dopamine helps transmit signals between the areas of the brain that produce smooth, purposeful movements such as eating, writing, and shaving. Early symptoms of the disease are subtle and typically worsen gradually; however, the disease progresses more quickly in some people than in others.

### Istradefylline

Istradefylline is an Adenosine A<sub>2A</sub> receptor antagonist, and is a novel non-dopaminergic pharmacologic approach to treating OFF episodes for people living with PD. Based on data from four clinical studies, Istradefylline taken as an adjunct to levodopa significantly improved OFF time and

demonstrated a well-tolerated safety profile. Istradefylline represents an important new treatment

option for patients with Parkinson's disease who experience 'OFF' episodes.

Adenosine A<sub>2A</sub> receptor, found at high levels in the basal ganglia, a region of the brain that controls movement. By blocking this receptor, Istradefylline can alter the release of neurotransmitters, chemical substances produced in response to nerve signals that allow nerve cells to communicate in the basal ganglia, in this way modulating motor activity.

### Clinical trial

The effectiveness of Istradefylline in treating "off" episodes in patients with PD who are already being treated with levodopa/carbidopa was shown in four 12-week placebo-controlled clinical studies that included a total of 1,143 participants. In all four studies, patients treated with Istradefylline experienced a statistically significant decrease from baseline in daily "off" time compared to patients receiving a placebo.

The safety and efficacy of Istradefylline for the adjunctive treatment to levodopa/carbidopa patients with Parkinson's disease experiencing "off" episodes were shown in four randomized, multicenter, double-

blind, 12-week, placebo-controlled trials. Patients enrolled in the trials had been treated with levodopa for at least one year and were experiencing at least two hours of “off” time per day. Patients continued levodopa and other Parkinson’s Disease medications during the trials. The trials measured the change from baseline in the daily awake percentage of “off” time, or the change from baseline in total daily “off” time, based on 24-hour diaries completed by patients.

The product has been marketed in Japan under the brand name Nourias since May 30, 2013. In Japan, Nourias is indicated for the improvement of the “wearing-off” phenomenon in patients with Parkinson’s disease on levodopa-containing preparations.

#### **Common adverse effects**

The most common adverse reactions observed in patients taking Istradefylline were involuntary muscle movement (dyskinesia), dizziness, constipation, nausea, hallucination and sleeplessness (insomnia). Patients should be monitored for development of dyskinesia or exacerbation of existing dyskinesia. If hallucinations, psychotic behavior, or impulsive/compulsive behavior occurs, a dosage reduction or stoppage of Istradefylline should be considered. Use of Istradefylline during pregnancy is not recommended. Women of childbearing potential should be advised to use contraception during treatment.

The FDA granted approval of Istradefylline (Nouriaz) to Kyowa Kirin, Inc.

#### **Dosage Forms and Strength:**

Tablets: 20 mg and 40 mg

#### **Indications and Usage:**

Istradefylline is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson’s disease (PD) experiencing “off” episodes

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