Nourianz™ (istradefylline) – New drug approval

- On August 27, 2019, the FDA announced the approval of Kyowa Kirin's Nourianz (istradefylline), as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes.

- 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.

    — An "off" episode is a time when a patient's medications are not working well, causing an increase in PD symptoms, such as tremor and difficulty walking.

- Nourianz is a novel adenosine A_{2A} receptor antagonist and it provides a non-dopaminergic pharmacologic approach to treating "off" episodes for people living with PD.

- The efficacy of Nourianz was established in four randomized, double-blind, placebo-controlled studies in 1,143 patients with PD experiencing "off" episodes. Study 1 was conducted in the U.S. and Canada, study 2 was conducted in the U.S., and studies 3 and 4 were conducted in Japan. The primary efficacy endpoint was 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 patient

    — In all four studies, patients treated with Nourianz experienced a statistically significant least squares mean difference (LSMD) from baseline in daily "off" time vs. placebo.

	Change from baseline in daily awake "off" time
	LSMD vs. placebo % awake "off" hours (p-value)
Study 1	
Nourianz 40 mg vs. placebo	-6.78 (p = 0.007)
Study 2	
Nourianz 20 mg vs. placebo	-4.57 (p = 0.025)

	Change from baseline in daily "off" time
	LSMD vs. placebo Hours (p-value)
Study 3	
Nourianz 20 mg vs. placebo	-0.65 (p = 0.028)
Nourianz 40 mg vs. placebo	-0.92 (p = 0.002)
Study 4	
Nourianz 20 mg vs. placebo	-0.76 (p = 0.006)
Nourianz 40 mg vs. placebo	-0.74 (p = 0.008)

- Warnings and precautions for Nourianz include dyskinesia, hallucinations/psychotic behavior, and impulse control/compulsive behavior.

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- The most common adverse reactions (≥ 5% and more frequent than placebo) with Nourianz use were dyskinesia, dizziness, constipation, nausea, hallucination, and insomnia.
- The recommended dosage of Nourianz is 20 mg orally once daily. The dosage may be increased to a maximum of 40 mg once daily. Initial dose titration is not required.
- Kyowa Kirin's launch plans for Nourianz are pending. Nourianz will be available as 20 mg and 40 mg tablets.