Xadago® (safinamide) – New drug approval

- On March 21, 2017, the FDA announced the approval of Newron Pharmaceuticals' Xadago (safinamide), indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

    — Xadago has not been shown to be effective as monotherapy for the treatment of PD.

- In the U.S., an estimated 50,000 people are diagnosed with PD each year and about one million people have the condition. PD is a neurological disease that typically affects people > 60 years of age.

- Cells in the brain that produce a chemical called dopamine become impaired or die. Dopamine helps transmit signals between the areas of the brain that produce smooth, purposeful movement. Patients typically experience muscular rigidity, resting tremor, or postural instability in combination with slow movement. During an "off" episode, patients' symptoms are increased.

- Xadago's mode of action is selective monoamine oxidase (MAO)-B inhibition. Blocking MAO-B activity is thought to result in an increase in dopamine levels and a subsequent increase in dopaminergic activity in the brain.

- The efficacy of Xadago was based on 2 double-blind, placebo-controlled, 24-week studies. The first study enrolled 645 patients and the second study enrolled 549 patients with PD experiencing "off" time while taking levodopa/carbidopa or other PD medications. The primary measure of effectiveness was the change from baseline in total daily "on" time without troublesome dyskinesia.

    — In study 1, Xadago significantly increased "on" time vs. placebo (Xadago 50 mg/day, least squares difference (LSD) = 0.50; 95% CI: 0.03, 0.96; p = 0.0356. Xadago 100 mg/day, LSD = 0.53; 95% CI: 0.07, 1.00; p = 0.0238).
    — In study 2, Xadago was significantly better vs. placebo for increasing "on" time (Xadago 100 mg/day, LSD = 0.99; 95% CI: 0.58, 1.39; p < 0.001).
    — In both studies, the increase in "on" time was accompanied by a reduction in "off" time and better scores on a measure of motor function assessed during "on" time than before treatment.

- Xadago is contraindicated in patients with concomitant use of the following drugs: other MAO inhibitors or other drugs that are potent inhibitors of MAO (eg, linezolid), opioid drugs (eg, tramadol, meperidine and related derivatives), selective norepinephrine reuptake inhibitors, tri-or tetra-cyclic or triazolopyridine antidepressants, cyclobenzaprine, methylphenidate, amphetamine, and their derivatives, St. John's wort and dextromethorphan; a history of a hypersensitivity to Xadago; and severe hepatic impairment (Child-Pugh C: 10 - 15).

- Other warnings and precautions of Xadago include hypertension, serotonin syndrome, falling asleep during activities of daily living, dyskinesia, hallucinations/psychotic behavior, impulse control/compulsive behaviors, withdrawal emergent hyperpyrexia and confusion, and retinal pathology.

- The most common adverse reactions (incidence on Xadago 100 mg/day at least 2% greater than placebo) with Xadago use were dyskinesia, fall, nausea, and insomnia.

- The recommended starting dose of Xadago is 50 mg orally once daily. After 2 weeks, the dosage may be increased to 100 mg once daily, based on individual need and tolerability.

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- US WorldMeds' launch plans for Newron's Xadago are pending. Xadago will be available as 50 mg and 100 mg tablets.