First Drug to Treat Tardive Dyskinesia Gets FDA Approval

On April 11, 2017, the FDA approved Ingrezza (valbenazine) as the first medication indicated to treat tardive dyskinesia in adult psychiatric patients. Tardive dyskinesia is a neurological dysfunction associated with symptoms of repetitive, involuntary movements, typically involving the tongue, jaw, and lips. This condition can further potentiate the elevated stigmatization of patients with mental illness. The incidence of tardive dyskinesia is most often seen in patients treated long-term with first generation antipsychotic medications.

The FDA approval for Ingrezza came following a phase III, randomized, double-blind, placebo-controlled trial referred to as *KINECT 3*. The trial consisted of an initial 6-week investigation, followed by a 48-week continuation, in which 234 patients were analyzed for changes in the Abnormal Involuntary Movement Scale (AIMS), which measures tardive dyskinesia severity. Patients were randomized to receive either placebo, 40 mg, or 80 mg daily. The results showed a significant improvement in AIMS score for patients taking the 80 mg dose.

Ingrezza carries no contraindications at this time but does warn about increased risk for somnolence and QT prolongation. Manufactured by Neurocrine Biosciences, Ingrezza is available in 40 mg capsules that have a white opaque body and purple cap. The initial dose of Ingrezza is 40 mg by mouth once daily with or without food. After one week, the dose should be titrated to the recommended dose of 80 mg once daily. The safety and effectiveness in pregnant and lactating patients has yet to be established. In patients with severe hepatic impairment, dosing should be limited to 40 mg daily. Ingrezza is not recommended in patients with severe renal impairment. Pricing is not available at this time but will be announced on May 1st, 2017.

The long-term efficacy of Ingrezza is still to be evaluated. Neurocrine Biosciences has begun studying its use to treat other disorders of spasticity, such as Tourette's syndrome. Given the large percentage of psychiatric patients that will develop tardive dyskinesia at some point in life, the approval of Ingrezza provides a new option for a condition previously deemed untreatable.

References:

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