FDA NEWS RELEASE

FDA Approves Drug with New Mechanism of Action for Treatment of Schizophrenia

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Español (https://www.fda.gov/news-events/press-announcements/la-fda-aprueba-un-medicamento-con-un-nuevo-mecanismo-de-accion-para-el-tratamiento-de-la)

Today, the U.S. Food and Drug Administration approved Cobenfy (xanomeline and trospium chloride) capsules for oral use for the treatment of schizophrenia in adults. It is the first antipsychotic drug approved to treat schizophrenia that targets cholinergic receptors as opposed to dopamine receptors, which has long been the standard of care.

“Schizophrenia is a leading cause of disability worldwide. It is a severe, chronic mental illness that is often damaging to a person’s quality of life,” said Tiffany Farchione, M.D., director of the Division of Psychiatry, Office of Neuroscience in the FDA’s Center for Drug Evaluation and Research. “This drug takes the first new approach to schizophrenia treatment in decades. This approval offers a new alternative to the antipsychotic medications people with schizophrenia have previously been prescribed.”

Schizophrenia can cause psychotic symptoms including hallucinations (such as hearing voices), difficulty controlling one’s thoughts and being suspicious of others. It can also be associated with cognitive problems and difficulty with social interactions and motivation. About 1% of Americans have this illness and globally it is one of the 15 leading causes (https://www.nimh.nih.gov/health/statistics/schizophrenia) of disability. Individuals with schizophrenia are at greater risk of dying at a younger age, and nearly 5% die by suicide.

Cobenfy’s effectiveness for the treatment of schizophrenia in adults was evaluated in two studies with identical designs. Study 1 and Study 2 were 5-week, randomized, double-blind, placebo-controlled, multi-center studies in adults with a diagnosis of schizophrenia according to DSM-5 criteria.

The primary efficacy measure was the change from baseline in the Positive and Negative Syndrome Scale (PANSS) total score at week 5. The PANSS is a 30-item scale that measures symptoms of schizophrenia. Each item is rated by a clinician on a seven-point scale. In both studies, the participants who received Cobenfy experienced a meaningful reduction in symptoms from baseline to Week 5 as measured by the PANSS Total Score compared to the placebo group.

The prescribing information includes warnings that Cobenfy can cause urinary retention, increased heart rate, decreased gastric movement or angioedema (swelling beneath the skin) of the face and lips. Cobenfy is not recommended for patients with mild hepatic (liver) impairment. It should not be used in patients with known hepatic impairment. There is also a risk of liver damage. Patients should stop using Cobenfy if experiencing signs or symptoms of substantial liver disease (including yellowing of the skin or the white part of the eyes, dark urine and unexplained itching). Cobenfy is substantially excreted by the kidney and is not recommended in patients with moderate to severe renal impairment.

Cobenfy should not be prescribed to patients with urinary retention, moderate or severe kidney or liver disease, gastric retention, untreated narrow-angle glaucoma or a history of hypersensitivity to either Cobenfy or its components.

The most common side effects of Cobenfy are nausea, indigestion, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia (increased heartbeat), dizziness and gastroesophageal reflux disease.

The approval of Cobenfy was granted to Bristol-Myers Squibb Company.

Related Information

- Schizophrenia - National Institute of Mental Health (https://www.nimh.nih.gov/health/statistics/schizophrenia)

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