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FDA grants approval for first drug to treat adults with tardive dyskinesia

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The U.S. Food and Drug Administration today approved Ingrezza (valbenazine) capsules to treat adults with tardive dyskinesia. This is the first drug approved by the FDA for this condition.

Tardive dyskinesia is a neurological disorder characterized by repetitive involuntary movements, usually of the jaw, lips and tongue, such as grimacing, sticking out the tongue and smacking the lips. Some affected people also experience involuntary movement of the extremities or difficulty breathing.

"Tardive dyskinesia can be disabling and can further stigmatize patients with mental illness," said Mitchell Mathis, M.D., director of the Division of Psychiatry Products in the FDA's Center for Drug Evaluation and Research. "Approving the first drug for the treatment of tardive dyskinesia is an important advance for patients suffering with this condition."

Tardive dyskinesia is a serious side effect sometimes seen in patients who have been treated with antipsychotic medications, especially the older medications, for long periods to treat chronic conditions, such as schizophrenia and bipolar disorder. Tardive dyskinesia can also occur in patients taking antipsychotic medications for depression and certain medications for gastrointestinal disorders and other conditions. It is unclear why some people who take these medications develop tardive dyskinesia yet others do not.

The efficacy of Ingrezza was shown in a clinical trial of 234 participants that compared Ingrezza to placebo. After six weeks, participants who received Ingrezza had improvement in the severity of abnormal involuntary movements compared to those who received placebo.

Ingrezza may cause serious side effects including sleepiness and heart rhythm problems (QT prolongation). Its use should be avoided in patients with congenital long QT syndrome or with abnormal heartbeats associated with a prolonged QT interval. Those taking Ingrezza should not drive or

operate heavy machinery or do other dangerous activities until it is known how the drug affects them.

The FDA granted this application Fast Track, Priority Review and Breakthrough Therapy designations.

The FDA granted approval of Ingrezza to Neurocrine Biosciences, Inc.

Source:

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm552418.htm