FDA approves first drug meant to ease Alzheimer's-linked agitation

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A medication to treat agitation in Alzheimer's patients now has approval

from the U.S. Food and Drug Administration.

The FDA gave supplemental approval to Otsuka Pharmaceutical Company Ltd., and Lundbeck Inc. for Rexulti (brexpiprazole) oral tablets on Thursday. Rexulti is the first FDA-approved treatment for these symptoms.

"Agitation is one of the most common and challenging aspects of care among patients with dementia due to Alzheimer's disease. "Agitation' can include symptoms ranging from pacing or restlessness to verbal and physical aggression," said Dr. Tiffany Farchione, director of the division of psychiatry in the FDA's Center for Drug Evaluation and Research.

"These symptoms are leading causes of assisted living or nursing home placement and have been associated with accelerated disease progression," she added in an agency news release.

The approval followed two 12-week studies. Participants were between 51 and 90 years of age, and had a probable diagnosis of Alzheimer's dementia, along with the type, frequency and severity of agitation behaviors that require medication.

Patients in the first study received either 1 or 2 milligrams (mg) of Rexulti. In the second study, they received 2 or 3 mg of Rexulti.

Over the 12 weeks, researchers looked for a change from baseline in a patient's Cohen-Mansfield Agitation Inventory (CMAI) score. The inventory is a tool that uses caregivers' input to rate the frequency of agitation on a scale from one to seven.

Patients who received 2 mg or 3 mg of Rexulti had statistically significant and clinically meaningful improvements in total CMAI scores compared to patients taking a placebo.

Alzheimer's disease is the most common form of dementia, a debilitating neurological condition with progressive decline. Many people with the condition require permanent at-home or residential care.

More than 6.5 million Americans have Alzheimer's disease. Agitation is a symptom that's complex and stressful.

The approval for Rexulti was made under the FDA's Fast Track designation, which speeds the review of drugs to treat serious conditions and satisfy an unmet medical need.

Recommendations call for new patients to take 0.5 mg once daily on days one to seven. They should step up to 1 mg daily on days eight through 14, and then to 2 mg daily starting on day 15.

The recommended target dose is 2 mg once daily.

Possible side effects include headache, colds, dizziness, urinary tract infection and sleep disturbances.

Rexulti will continue to carry a Boxed Warning designation for medications in this class. Elderly patients with dementia-related psychosis who are being treated with antipsychotic drugs are at an increased risk of death.

More information: The U.S. Centers for Disease Control and Prevention has more on Alzheimer's disease and related dementias.