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Japan's Otsuka Pharma gets US FDA nod for drug to treat agitation during Alzheimer's

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First drug to treat agitation symptoms associated with dementia due to Alzheimer's Disease

The US Food and Drug Administration (FDA) has announced the supplemental approval of Rexulti (brexpiprazole) oral tablets for the treatment of agitation associated with dementia due to Alzheimer's disease. This is the first FDA-approved treatment option for this indication.

The supplemental approval of Rexulti has been granted to Japanese pharmaceutical firm Otsuka Pharmaceutical Company, and Denmark-based Lundbeck Inc.

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.

The recommended starting dosage for the treatment of agitation associated with dementia due to Alzheimer's disease is 0.5 mg taken once daily on days 1 to 7. Patients should increase the dosage on days 8 through 14 to 1 mg once daily, and on day 15 to 2 mg once daily. The recommended target dose is 2 mg once daily. The dosage can be increased to the maximum recommended daily dosage of 3 mg once daily after at least 14 days, based on clinical response and tolerability.