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Otsuka and Lundbeck Announce U.S. Food and Drug Administration (FDA) Approval of supplemental New Drug Application (sNDA) for REXULTI® (brexpiprazole) for the Treatment of Agitation Associated with Dementia due to Alzheimer's Disease

Otsuka Pharmaceutical, Co. Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) announce the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) of REXULTI® (brexpiprazole) for use in the treatment of agitation associated with dementia due to Alzheimer's disease.

This approval makes REXULTI the first and only pharmacological treatment approved in the U.S. for agitation associated with dementia due to Alzheimer's disease. Agitation is a common neuropsychiatric symptom in Alzheimer's dementia and one of the most complex and stressful aspects of caring for people living with the condition. It is reported in approximately half of people with Alzheimer's dementia and is associated with earlier nursing home placement. REXULTI is not indicated as an as-needed ("PRN") treatment for agitation associated with dementia due to Alzheimer's disease.

Makoto Inoue, president and representative director of Otsuka, commented, "Today marks a major milestone for patients, caregivers, and families navigating the complexities of agitation associated with dementia due to Alzheimer's disease. Otsuka Pharmaceutical will continue its efforts to engage and provide options for those impacted by this devastating condition."

Deborah Dunsire, CEO and president, Lundbeck, said, "This approval is a testament to our commitment and unwavering support of patients and caregivers to lessen the symptoms of agitation associated with dementia due to Alzheimer's disease. We look forward to offering this first FDA-approved treatment option to address this significant unmet need for patients. We are grateful to the patients and caregivers who participated in these important trials."

The FDA previously granted priority review for the sNDA, a designation for a drug application that represents a significant improvement in the safety and/or effectiveness of the treatment, diagnosis, or prevention of a serious medical condition.

The submission was based on two Phase 3, 12-week, randomized, double-blind, placebo-controlled fixed-dose studies that evaluated the frequency of agitation symptoms in patients with dementia due to Alzheimer's disease based on the Cohen-Mansfield Agitation Inventory (CMAI) total score. The primary endpoint was a change in agitation symptom frequency (CMAI total score) from baseline at Week 12 in both studies. Overall, the data showed brexpiprazole as being well-tolerated with a low incidence of discontinuations, and with a safety profile consistent with the known safety profile of brexpiprazole in other indications.