October 31, 2023

Company Name	Otsuka Holdings Co., Ltd.
Name of Representative	Tatsuo Higuchi President and Representative Director, CEO
Code Number	4578, Prime market of the Tokyo Stock Exchange
Contact	Yuji Kogure Director, Investor Relations Department (Phone: +81-3-6361-7411)

Otsuka Applies in Japan for the Additional Indication for Agitation Associated with Dementia due to Alzheimer's Disease for Rexulti® (brexpiprazole)

Otsuka Pharmaceutical Co., Ltd. (Otsuka) announces that it has filed an application in Japan for an additional indication for Rexulti® (generic name: brexpiprazole) in the treatment of agitation associated with dementia due to Alzheimer's disease. If approved, brexpiprazole would be the first pharmacological treatment indicated for agitation in patients with dementia due to Alzheimer's disease in Japan.

The phase 3 clinical trial in Japan evaluated the efficacy and safety of brexpiprazole (1mg/day and 2mg/day) versus placebo over ten weeks in the treatment of 410 adult patients aged 55 to 90 with agitation associated with dementia due to Alzheimer's disease. The study's primary endpoint was attained, demonstrating a statistically significant improvement in the Cohen-Mansfield Agitation Inventory (CMAI) total score of the groups administered brexpiprazole 1mg/day or 2mg/day compared with the placebo group. Improvement was also observed in secondary endpoints such as the Clinical Global Impression-Severity Illness (CGI-S) score in the 1mg/day and 2mg/day brexpiprazole groups compared with the placebo group. Brexpiprazole was generally well tolerated, and no new safety signals were observed.

Otsuka will continue to deliver innovative products to meet unmet medical needs around the world.