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Otsuka Pharmaceutical announces positive results of phase III trial in Japan showing reduced agitation in patients with Alzheimer's dementia treated with brexpiprazole

Otsuka Pharmaceutical Co., Ltd. (Otsuka) announces positive results from a phase III clinical trial in Japan for brexpiprazole in the treatment of agitation associated with Alzheimer's dementia.

The trial (ClinicalTrials.gov Identifier NCT03620981) was designed to assess the efficacy, safety and tolerability of one daily fixed dose (1mg/day or 2mg/day) of brexpiprazole in the treatment of patients with agitation associated with Alzheimer's dementia. It was a 10-week, multicenter, randomized, double-blind, placebo-controlled trial that comprised 410 patients, aged 55 to 90 years, with agitation associated with Alzheimer's dementia. The primary endpoint was mean change from the baseline in the Cohen-Mansfield Agitation Inventory (CMAI) total score at week 10.

The study's primary endpoint was attained, demonstrating a statistically significant improvement in the CMAI total score of the groups administered brexpiprazole 1mg/day (p value=0.0175) or 2mg/day (p value<0.0001) compared with the placebo group.

Improvement was also observed in secondary endpoints such as Clinical Global Impression-Severity Illness (CGI-S) score in the 1 mg/day and 2 mg/day brexpiprazole groups compared with the placebo group. Brexpiprazole was generally well tolerated, and no new safety signals were observed.

Additional analysis of the trial results is planned to further interpret the efficacy and safety of brexpiprazole for the treatment indication.

Based on this study outcome Otsuka is planning a regulatory filing in Japan later in 2023 for an additional treatment indication for brexpiprazole.
If approved, brexpiprazole would be the first pharmacological treatment indicated for agitation in patients with Alzheimer's dementia in Japan.

About brexpiprazole
Brexpiprazole was discovered by Otsuka and is being co-developed by Otsuka and Lundbeck. Brexpiprazole was

approved in the U.S. in July 2015 as an adjunctive therapy to antidepressants in adults with major depressive disorder and as a treatment in adults with schizophrenia. Brexpiprazole has also been approved in over 60 countries. In May 2023, the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application (sNDA) of brexpiprazole as the first-and-only drug approved for use in the treatment of agitation associated with dementia due to Alzheimer's disease.