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## Otsuka Announces Phase 3 Topline Results of AVP-786 in the Treatment of Agitation Associated with Dementia due to Alzheimer’s Disease

Otsuka Pharmaceutical Co., Ltd. (Otsuka) and its U.S. subsidiaries, Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC) announce topline results of the phase 3 clinical trial of AVP-786 in the treatment of agitation associated with dementia due to Alzheimer’s disease (Trial 17-AVP-786-305; NCT03393520). A statistically significant difference was not achieved on the primary efficacy endpoint, mean change from baseline to week 12 in the Cohen-Mansfield Agitation Inventory (CMAI) total score between AVP-786 and placebo.

There was one treatment-emergent adverse event (TEAE) with an incidence rate of more than 5% in patients treated with AVP-786 and greater than placebo which was Fall; 16 (8.6%) in AVP-786 high dose, 18 (9.1%) in AVP-786 low dose and 6 (2.8%) placebo. There were 4 deaths reported in the trial; 1 (0.5%) in the AVP-786 low dose group and 3 (1.4%) in the placebo group.

Full study results are not yet available. Further prespecified and exploratory analyses of the data set will be conducted to determine the full potential of AVP-786 in the treatment of agitation associated with dementia due to Alzheimer’s disease. Otsuka intends to submit the trial results for scientific publication at a later date.

“While the result of this trial is disappointing, we plan to analyze the full data set to determine the future potential of AVP-786 in the treatment of agitation associated with dementia due to Alzheimer’s disease. In 2023, Otsuka became the first company to get a drug approved for this patient population and we are committed to expanding and innovating in this area,” said John Kraus, M.D., Ph.D., executive vice president and chief medical officer at Otsuka. “We are deeply grateful to all of the study participants, their caregivers, and the investigators who took part in this trial and contributed to this research.”

### About agitation associated with dementia due to Alzheimer’s disease

Agitation associated with dementia due to Alzheimer’s disease is a common neuropsychiatric symptom that is reported in approximately half of all patients with Alzheimer’s dementia. The condition has a large impact on the quality of life for the patients, family members, and caregivers.<sup>1,2</sup> Agitation associated with dementia due to Alzheimer’s disease covers a large group of behaviors such as pacing, gesturing, profanity, shouting, shoving, and hitting.<sup>3</sup> Symptoms of this condition are also a consistent predictor of nursing home admission.<sup>4,5,6</sup>

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