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For Immediate Release

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Otsuka's Subsidiary Avanir Pharmaceuticals Reports Top-line Data from Second Phase 3 Trial Evaluating Investigational AVP-786 for the Treatment of Moderate-to-Severe Agitation in Patients with Alzheimer's Dementia

Otsuka Pharmaceutical Co., Ltd. announces that its U.S.-based, indirect subsidiary Avanir Pharmaceuticals, Inc. reports results from the second study of its phase 3 clinical development program investigating the efficacy, safety and tolerability of AVP-786 (deudextromethorphan hydrobromide [d6-DM]/quinidine sulfate [Q]) for the treatment of moderate-to-severe agitation in patients with Alzheimer's dementia.

The trial did not meet its primary endpoint and key secondary endpoints. Patients treated with AVP-786 did not experience a statistically significant improvement in agitation compared to patients treated with placebo, as measured by the Cohen-Mansfield Agitation Inventory (CMAI, a 29-item scale to measure agitation), the trial's primary endpoint.

This was a 12-week, multicenter, randomized, double-blind, and placebo-controlled study.

The most common adverse events in patients receiving AVP-786 versus those receiving placebo were falls, urinary tract infection, and somnolence (greater than 5% incidence). No deaths were considered related to treatment.