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For Immediate Release

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Otsuka and Lundbeck announce decision to continue phase III clinical trial evaluating brexpiprazole for treatment of agitation in patients with Alzheimer's-type dementia

Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) announce the decision to continue the recruitment of patients in the phase III clinical trial of brexpiprazole in the treatment of agitation in patients with dementia of the Alzheimer's type. The decision to continue the trial is based on the results of an independent interim analysis, supporting to progress the trial to the planned full enrollment of 330 patients.

The continuation of the study enables us to further explore the efficacy of brexpiprazole to address the high medical need in patients suffering from agitation in Alzheimer's type dementia. Completion of the trial is expected in the first half of 2022.

About the study

The trial was designed to assess the safety, tolerability and efficacy of brexpiprazole in the treatment of patients with agitation in Alzheimer's dementia. The trial consisted of a 12-week double-blind treatment period with a 30-day follow-up. The trial population was planned to include 330 male and female patients, aged 55 to 90 years (inclusive), with a diagnosis of probable Alzheimer's disease.

The primary outcome was the change in the CMAI total score. The key secondary outcome was the change in the Clinical Global Impression – Severity of Illness (CGI-S) score, as related to symptoms of agitation. Patients participating in the trial are from countries including Bulgaria, Hungary, Serbia, Slovakia, Spain, Ukraine, and the U.S. Approximately half of the participants are living at home and the rest are institutionalized.

As agreed with the FDA, an interim analysis conducted by an independent data monitoring committee assessed the efficacy on the CMAI total score, in accordance with pre-specified criteria when 255 subjects had completed the trial.