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For Immediate Release

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INVESTIGATIONAL COMPOUND BREXPIPIRAZOLE MET PRIMARY AND SECONDARY STUDY ENDPOINTS IN PHASE III CLINICAL TRIAL IN MAJOR DEPRESSIVE DISORDER (MDD)

Clinical trial findings presented by Otsuka and Lundbeck at the European Psychiatry Association Congress

Otsuka Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Otsuka Holdings Co. Ltd., and H. Lundbeck A/S presented results from a completed phase III study of investigational compound brexpiprazole in patients with major depressive disorder (MDD). Results were presented in a poster session at the 22nd European Psychiatry Association Congress (EPA) now underway.

[Study Method]

This was a phase III, randomized, placebo-controlled study investigating the efficacy and safety of brexpiprazole as adjunctive therapy to antidepressant therapy (ADT) in subjects with Major Depressive Disorder (MDD) who demonstrated inadequate responses to ADT monotherapy. 379 patients were randomized to double-blind adjunctive brexpiprazole (2mg/day, n=188) or placebo (n=191).

[Results]

This phase III study showed statistically significant improvement in mean MADRS total score for patients receiving adjunctive brexpiprazole compared to patients receiving placebo. MADRS (Montgomery-Åsberg Depression Rating Scale) is a commonly used scale to assess the range of symptoms in patients with major depression. The primary efficacy endpoint of the phase III trial was the change in the MADRS total score during the 6-week randomized treatment phase.

In addition, on all secondary endpoints brexpiprazole showed a statistically significant advantage over placebo.

The most common adverse events (occurring in > 5% of brexpiprazole patients and a higher percentage than in patients receiving placebo) during this Phase III study were weight gain (8.0% vs. 1.5%) and akathisia (7.4% vs. 1.0%).

The consolidated business forecast of fiscal 2013 announced by Otsuka Holdings on November 13, 2013 will not be changed.