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For Immediate Release

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Otsuka and Lundbeck to present new data on brexpiprazole in major depressive disorder (MDD) at European Psychiatry Association 2014 Congress

Otsuka Pharmaceutical Co., Ltd., a subsidiary company of Otsuka Holdings Co., Ltd., and H. Lundbeck A/S today announced that the first phase III data on their investigational compound brexpiprazole will be presented in an upcoming poster session at the 22nd European Psychiatry Association Congress (EPA) on March 2, 2014.

(Tokyo, Japan and Copenhagen, Denmark, Friday, January 24, 2014) – Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) today announced that the first phase III data on their investigational compound brexpiprazole will be presented in an upcoming poster session at the 22nd European Psychiatry Association Congress (EPA) on March 2, 2014.

Data will be presented from a completed phase III, randomized, placebo-controlled study investigating the effect of brexpiprazole as adjunctive therapy to antidepressant therapy in patients with major depressive disorder (MDD). Overall, brexpiprazole demonstrated efficacy and was well tolerated as an adjunctive treatment for MDD patients with an inadequate response to antidepressant treatment.

At the EPA congress, highlighted data on brexpiprazole as adjunctive therapy to anti-depressant therapy in MDD will include:

- Statistically significant improvements in mean MADRS total score for patients receiving adjunctive brexpiprazole compared with placebo. MADRS (Montgomery–Åsberg Depression Rating Scale) is a commonly used scale to assess the range of symptoms in patients with major depression
- A statistically significant advantage over placebo on all secondary endpoints
- Most common adverse events reported in the patients receiving adjunctive brexpiprazole were weight gain and akathisia (inner restlessness)
- Over 90% of patients completed the randomized phase of the trial

Additional information provided in the poster presentation at the EPA congress will be publicly disclosed at that time.

Otsuka and Lundbeck are running an extensive development program for brexpiprazole. Three additional studies in depression and schizophrenia will conclude in the first half of 2014. Phase III clinical trials are also underway in patients with agitation associated with dementia of the Alzheimer's type, and adult patients with post-traumatic stress disorder.

About brexpiprazole (OPC-34712)

Brexpiprazole is a novel investigational psychotherapeutic compound discovered by Otsuka and under co-development with Lundbeck. Brexpiprazole is a so-called serotonin dopamine activity modulator (SDAM) acting as a partial agonist at 5-HT_{1A} and dopamine D₂ receptors at similar potency, and an antagonist at 5-HT_{2A} and noradrenaline alpha_{1B} receptors. It is hypothesized to provide improved efficacy and tolerability over established adjunctive treatments for MDD.

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