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OTSUKA AND LUNDBECK'S BREXPIPRAZOLE DEMONSTRATES STATISTICALLY SIGNIFICANT EFFECTS IN NEW PHASE III STUDIES IN ADULT PATIENTS WITH SCHIZOPHRENIA PRESENTED AT THE AMERICAN COLLEGE OF NEUROPSYCHOPHARMACOLOGY ANNUAL MEETING

Otsuka Pharmaceutical Co., Ltd., a wholly-owned subsidiary of Otsuka Holdings Co. Ltd., and H. Lundbeck A/S today announced the presentation of Phase III study results evaluating the effects of an investigational compound, brexpiprazole, as monotherapy in adult patients with schizophrenia at the 53rd Annual Meeting of the American College of Neuropsychopharmacology (ACNP) in Phoenix, Arizona.

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Tokyo, Japan and Valby, Denmark – December 11, 2014 – Otsuka Pharmaceutical Co., Ltd. (Otsuka) and H. Lundbeck A/S (Lundbeck) today announced the presentation of Phase III study results evaluating the effects of an investigational compound, brexpiprazole, as monotherapy in adult patients with schizophrenia at the 53rd Annual Meeting of the American College of Neuropsychopharmacology (ACNP) in Phoenix, Arizona. The data were shared in two poster presentations, "A Multicenter, Randomized, Controlled, Phase III Trial of Fixed-dose Brexpiprazole for the Treatment of Adults with Acute Schizophrenia" and "Brexpiprazole for the Treatment of Acute Schizophrenia: A Randomized, Controlled Trial."

"Schizophrenia is a debilitating condition and patients often struggle to maintain a treatment regimen for multiple reasons, including lack of efficacy and undesired side effects," said Dr. Christoph U. Correll, Professor of Psychiatry, Hofstra North Shore LIJ School of Medicine and Medical Director, Recognition and Prevention Program (RAP), The Zucker Hillside Hospital, both in New York, and lead author of one of the study reports. "Therefore, additional treatment options are needed. The signals of efficacy, together with the favorable side effect profile observed in this study, support the use of brexpiprazole in this patient population."

Schizophrenia Study Results

The poster, "Brexpiprazole for the Treatment of Acute Schizophrenia: A Randomized, Controlled Trial," (NCT01396421) evaluated the efficacy and tolerability of brexpiprazole in adult patients with acute schizophrenia. The pivotal Phase III trial randomized 636 patients with acute schizophrenia to fixed doses of brexpiprazole (0.25mg, 2mg or 4mg) or placebo (randomized 1:2:2:2) respectively for 6 weeks.

The results indicated:

- Brexpiprazole 4mg and 2mg demonstrated greater improvement than placebo in the primary endpoint of change from baseline to Week 6 in Positive and Negative Syndrome Scale (PANSS) Total Score (4mg: -19.65, p=0.0006 and 2mg: -20.73, p=<0.0001 vs. placebo -12.01; 0.25mg was similar to placebo -14.90).
- Key secondary endpoint results, the change in Clinical Global Impression-Severity Scale (CGI-S) score at Week 6, supported the primary results (4mg: -1.20, p=0.0012; 2mg: -1.15, p=0.0056 vs. placebo -0.82)
- Overall, approximately 65% of patients completed the 6-week study. Discontinuations due to adverse events were 13.3%, 8.2%. 9.4% and 17.4%, while discontinuations due to lack of efficacy were 7.8%, 9.3%, 3.9% and 9.8% in the brexpiprazole 0.25mg, 2mg, 4mg and placebo groups, respectively.
- The most frequently reported treatment-emergent adverse events (TEAEs; greater than 5% in at least one brexpiprazole treatment arm and more frequent than placebo) were diarrhea (5.6%, 1.6%, 3.9% vs. 1.6%), nausea (1.1%, 5.5%, 3.3% vs. 4.3%), akathisia (0%, 4.4% ,7.2% vs. 2.2%) and headache (10.0%, 9.3%, 12.2% vs. 8.2%) in the brexpiprazole 0.25mg, 2mg, 4mg, versus placebo groups, respectively.

The poster, "A Multicenter, Randomized, Controlled, Phase III Trial of Fixed-dose Brexpiprazole for the Treatment of Adults with Acute Schizophrenia," (NCT01393613) showcased results from a pivotal Phase III trial that randomized 674 patients with acute schizophrenia to fixed doses of brexpiprazole (1mg, 2mg, 4mg) or placebo (2:3:3:3) respectively for 6 weeks.

The results indicated:

- Brexpiprazole 4mg showed improvement over placebo in the primary endpoint of PANSS Total Score from baseline to Week 6 (-20.0 vs. -13.5, p=0.0022), while the 2mg (-16.6) and 1mg (-16.9) doses showed numeric improvement versus placebo (-13.5, p>0.05).
- Key secondary endpoint results, the change in CGI-S score versus placebo at Week 6, supported the primary results (4mg: -1.2, p=0.0015; 2mg: -1.0, p>0.05; 1mg: -0.9, p>0.05 vs. placebo: -0.8).
- Overall, approximately 68% of patients completed the 6-week study. Discontinuations due to adverse events were 9.2%, 5.9%. 7.1% and 12.0%, while discontinuations due to lack of efficacy were 7.5%, 10.8%, 8.7% and 11.4% in the brexpiprazole 1mg, 2mg, 4mg and placebo groups, respectively.
- The most frequently reported TEAEs (greater than 5% in at least one brexpiprazole treatment arm and more frequent than placebo) were dyspepsia (5.8%, 3.8%, 3.3% vs. 3.3%), insomnia (12.5%, 13.4%, 15.2% vs. 14.7%) and agitation (8.3%, 8.6%, 7.1% vs. 7.1%) for 1mg, 2mg, and 4mg brexpiprazole treatment groups versus placebo, respectively.

"We and Lundbeck are proud to present these data results for the first time as a critical part of the clinical program supporting the safety and efficacy of brexpiprazole in adults with schizophrenia," said William Carson, MD, CEO, Otsuka Pharmaceutical Development & Commercialization, Inc. "It is our hope that brexpiprazole will offer schizophrenia patients another treatment option to manage symptoms while living with this disease."

"Schizophrenia is a complicated disease experienced by approximately 2.4 million adults in the U.S., and having more treatment options is critical to addressing unmet needs. We still lack a truly effective and

predictable path toward treatment," said Anders Gersel Pedersen, MD, EVP and head of R&D in Lundbeck. "While advances have been made, we believe brexpiprazole can be a strong new treatment choice for these patients."

Otsuka and Lundbeck also presented results from two Phase III studies evaluating the effect of brexpiprazole as adjunctive treatment to antidepressant therapy (ADT) in patients with major depressive disorder (MDD) at ACNP. The data were shared in a poster presentation, "Efficacy and Safety of Adjunctive Brexpiprazole (OPC-34712) in Major Depressive Disorder: Results of Two Pivotal Clinical Studies."

About Brexpiprazole (OPC-34712)

Brexpiprazole is a novel investigational psychotropic compound discovered by Otsuka and under co-development with Lundbeck. Brexpiprazole is a serotonin-dopamine activity modulator (SDAM) that acts as a partial agonist at 5-HT_{1A} and dopamine D_2 receptors, and an antagonist at 5-HT_{2A} and noradrenaline $alpha_{1B/2C}$ receptors, all with similar high potency (< 1 nM). A New Drug Application for brexpiprazole has been filed with the U.S. Food and Drug Administration (FDA) and the PDUFA date is in July 2015.