Takeda and Lundbeck Present Vortioxetine Data at the American Psychiatric Association (APA) 2016 Annual Meeting

Deerfield, IL, May 16, 2016 – Takeda Pharmaceuticals U.S.A., Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited (TSE:4502) and Lundbeck today announced that additional data from clinical studies evaluating the efficacy and safety of vortioxetine in adults with major depressive disorder (MDD) will be presented during the American Psychiatric Association (APA) 2016 Annual Meeting in Atlanta, Georgia, to be held on May 14-18, 2016.

Five Takeda- and Lundbeck-sponsored posters appearing at the APA meeting will discuss the efficacy and safety of vortioxetine, including three that will discuss data from clinical studies evaluating the effect of vortioxetine on cognitive dysfunction in MDD patients. One additional poster will present the 6-month interim results from a 2-year prospective observational cohort study of cognitive dysfunction as a potential predictor of relapse in MDD patients in remission. A final poster will include pre-clinical data.

“Takeda and our partners at Lundbeck are proud to present data at this year’s APA that demonstrate the depth and breadth of the growing body of vortioxetine scientific data,” said Charlie Baum, M.D., Vice President and Head, U.S. Medical and Scientific Affairs, Takeda.

A full list of Takeda- and Lundbeck-sponsored abstracts to be presented at the APA 2016 Annual Meeting is as follows:

- Poster P6-128: Comparative evaluation of vortioxetine as a switch therapy in patients with major depressive disorder (Thase M, Danchenko N, Brignone M, et al.) Monday, May 16
- Poster P8-145: Minimal clinically important difference and treatment response determination for UCSD performance-based skills assessment in major depressive disorder (Harvey P, Jacobson W, Zhong W, et al.) Tuesday, May 17
- Poster P8-085: Efficacy of vortioxetine on cognitive function in working subjects with major depressive disorder (Lam R, McIntyre R, Florea I, et al.) Tuesday, May 17
- Poster P6-112: Residual patient-reported cognitive dysfunction: a potential predictor for relapse in MDD? (Saragoussi D, Touya M, Haro JM, et al.) Monday, May 16

Brintellix (vortioxetine) is indicated for the treatment of MDD in adults. On May 2, it was announced that the trade name for vortioxetine was changed to Trintellix with product availability beginning in June 2016. Please see the press release for additional details.

About Brintellix (vortioxetine) renamed Trintellix (vortioxetine)

The mechanism of the antidepressant effect of Brintellix is not fully understood. It is an inhibitor of serotonin (5-HT) reuptake and that is thought to be a mechanism of its action. It is also an agonist at 5-HT1A receptors, a partial agonist at 5-HT1B receptors and an antagonist at 5-HT3, 5-HT1D and 5-HT7 receptors. The contribution of each of these activities to Brintellix’s antidepressant effect has not been established. It is considered to be the first and only compound with this combination of pharmacodynamic activity. The clinical relevance of this is unknown.

Brintellix was discovered by Lundbeck researchers in Copenhagen, Denmark. The clinical trial program in the U.S. was conducted jointly by Lundbeck and Takeda, and Takeda holds the new drug application for the U.S. market. Brintellix is a
WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a trend toward reduced risk with antidepressant use in patients aged 65 and older.

In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

BRINTELLIX has not been evaluated for use in pediatric patients.

TRACTIONINDICATIONS

Hypersensitivity: Hypersensitivity to vortioxetine or any components of the BRINTELLIX formulation. Angioedema has been reported in patients treated with BRINTELLIX.

Monoamine Oxidase Inhibitors (MAOIs): Due to an increased risk of serotonin syndrome, do not use MAOIs intended to treat psychiatric disorders with BRINTELLIX or within 21 days of stopping treatment with BRINTELLIX. Do not use BRINTELLIX within 14 days of stopping an MAOI intended to treat psychiatric disorders. Do not start BRINTELLIX in a patient who is being treated with linezolid or intravenous methylene blue.

WARNINGS AND PRECAUTIONS

Clinical Worsening and Suicide Risk: All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality (anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania), especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Families and caregivers of patients being treated with antidepressants for MDD or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients daily.
Serotonin Syndrome: The development of a potentially life-threatening serotonin syndrome has been reported with serotonergic antidepressants (SNRIs, SSRIs, and others), including BRINTELLIX, when used alone but more often when used concomitantly with other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort), and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezoid and intravenous methylene blue). Serotonin syndrome symptoms may include mental status changes (eg, agitation, hallucinations, delirium, and coma), autonomic instability (eg, tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (eg, tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhea). If such symptoms occur, discontinue BRINTELLIX and any concomitant serotonergic agents, and initiate supportive symptomatic treatment. If concomitant use of BRINTELLIX is clinically warranted, patients should be made aware of and monitored for potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases.

Abnormal Bleeding: Treatment with serotonergic antidepressants (SSRIs, SNRIs, and others) may increase the risk of abnormal bleeding. Patients should be cautioned about the increased risk of bleeding when BRINTELLIX is coadministered with NSAIDs, aspirin, or other drugs that affect coagulation.

Activation of Mania/Hypomania: Activation of mania/hypomania can occur with antidepressant treatment. Prior to initiating treatment with an antidepressant, screen patients for bipolar disorder. As with all antidepressants, use BRINTELLIX cautiously in patients with a history or family history of bipolar disorder, mania, or hypomania.

Angle-Closure Glaucoma: The pupillary dilation that occurs following use of many antidepressant drugs, including BRINTELLIX, may trigger an angle-closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy.

Hyponatremia: Hyponatremia has occurred as a result of serotonergic drugs and in many cases, appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). Elderly patients and patients taking diuretics or who are otherwise volume-depleted can be at greater risk. More severe or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death. Discontinue BRINTELLIX in patients with symptomatic hyponatremia and initiate appropriate medical intervention.

Adverse Reactions: The most commonly observed adverse reactions for BRINTELLIX in 6- to 8-week placebo-controlled studies (incidence ≥5% and at least twice the rate of placebo) were by dose (5 mg, 10 mg, 15 mg, 20 mg) vs placebo: nausea (21%, 26%, 32%, 32% vs 9%), constipation (3%, 5%, 6%, 6% vs 3%), and vomiting (3%, 5%, 6%, 6% vs 1%).

Drug Interactions: Concomitant administration of BRINTELLIX and strong CYP2D6 inhibitors or strong CYP inducers may require a dose adjustment of BRINTELLIX.

INDICATION
BRINTELLIX is indicated for the treatment of major depressive disorder in adults.

Please see Full Prescribing Information and Medication Guide for BRINTELLIX.

About Takeda Pharmaceuticals U.S.A., Inc.
Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine.

The company has a commercial presence covering around 70 countries, with particular strength in Asia, North America, Europe and fast-growing emerging markets including Latin America, Russia-CIS and China. Areas of R&D focus include central nervous system, cardiovascular and metabolic, gastroenterology, oncology, and vaccines.

Takeda Pharmaceuticals U.S.A., Inc. is located in Deerfield, Ill., and is the U.S. marketing and sales organization of Takeda Pharmaceutical Company Limited.

Additional information about Takeda is available through its corporate website, www.takeda.com, and additional information about Takeda Pharmaceuticals U.S.A., Inc. is available through its website, www.takeda.us.

About Takeda Pharmaceutical Company Limited
Located in Osaka, Japan, Takeda (TSE: 4502) is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine.

Additional information about Takeda is available through its corporate website, www.takeda.com.

About Lundbeck
Lundbeck is a global pharmaceutical company specialized in brain diseases. For more than 70 years, we have been at the forefront of research within neuroscience. The key areas of focus are Alzheimer’s disease, depression, Parkinson’s disease and psychosis.

An estimated 700 million people worldwide are living with brain disease and far too many suffer due to inadequate treatment, discrimination, a reduced number of working days, early retirement and other unnecessary consequences. Every day, we strive for improved treatment and a better life for people living with brain disease – we call this Progress in Mind.

Our approximately 5,500 employees in 57 countries are engaged in the entire value chain throughout research, development, production, marketing and sales. Our pipeline consists of several late-stage development programs and our products are available in more than 100 countries. We have research centres in China and Denmark and production facilities in China, Denmark, France and Italy. Lundbeck generated core revenue of DKK 14.6 billion in 2015 (EUR 2 billion; USD 2.2 billion).

For additional information, we encourage you to visit our corporate site www.lundbeck.com and connect with us on Twitter at @Lundbeck.

Lundbeck in the U.S.
In the U.S., Lundbeck employs more than 800 people focused solely on accelerating therapies for brain diseases. With a special commitment to the lives of patients, families and caregivers, Lundbeck US actively engages in hundreds of initiatives each year that support our patient communities.

To learn more, visit us at www.LundbeckUS.com and connect with us on Twitter at @LundbeckUS

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Contacts:

Roseanne Durril
Takeda Pharmaceutical U.S.A., Inc
Tel: +1-224-554-1474
Email: roseanne.durril@takeda.com

Ashleigh Duchene
Lundbeck
Tel: +1-847-282-1164
Email: aduc@lundbeck.com