News Release

Brintellix® (vortioxetine) for the treatment of major depressive disorder in adults is now available in U.S. pharmacies

Following initial availability through wholesalers soon after its September 30 approval by the U.S. Food and Drug Administration, Brintellix is now available in pharmacies across the United States

Valby, Denmark and Osaka, Japan, 21 January 2014 - H. Lundbeck A/S (Lundbeck) and Takeda Pharmaceutical Company Limited (Takeda) jointly announced today that Brintellix (vortioxetine), for the treatment of major depressive disorder (MDD) in adults, is available in pharmacies across the United States (U.S.) – following initial availability through wholesalers soon after its September 30 approval by the U.S. Food and Drug Administration. Brintellix is a once-daily oral antidepressant available in a range of doses, to help address the variability of patient needs.

"Our passion for helping people living with MDD has been the inspiration for advancing Brintellix from the laboratory through clinical studies, and now into the hands of those who need it," said Staffan Schüberg, president, Lundbeck US. "This same passion fuels our ongoing commitment to supporting people with this often chronic and complex disease."

The comprehensive clinical trial program evaluating the safety and efficacy of Brintellix for approval in the U.S. was comprised of seven positive pivotal studies, including six 6-8 week short-term studies and one 24-64 week long-term maintenance study that demonstrated statistically significant improvements in overall symptoms of depression in adults with MDD. The primary rating scales utilized in the short-term studies included mean change from baseline to endpoint in the Montgomery-Asberg Depression Rating Scale (MADRS) or the Hamilton Depression Rating Scale (HAMD-24) total score. In addition, the long-term maintenance study also showed Brintellix treatment resulted in a statistically significant longer time to recurrence of depressive episodes (defined as a MADRS total score greater than or equal to 22 or as judged by the investigator) compared to placebo.

"MDD continues to be a challenging condition to manage, and we are proud to make Brintellix available as a new treatment option for people struggling with major depression," said Douglas Cole, president, Takeda Pharmaceuticals U.S.A., Inc.

Fewer than half of people with depression worldwide are treated, and the burden of depression is expected to continue to rise globally.[1] In fact, clinical depression was the second-leading cause of global disability in 2010.[2] In the U.S., it's been estimated that more than 30 million people have suffered with MDD over a lifetime.[3]

About Brintellix (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 trademark of H. Lundbeck A/S and is used under license by Takeda Pharmaceuticals America, Inc.

The World Health Organization has issued an Anatomical Therapeutic Chemical (ATC) code for Brintellix that places it in the category of "Other" antidepressants.

The most commonly observed adverse events in MDD patients treated with Brintellix in 6-8 week placebo-controlled studies (incidence greater than or equal to 5 percent and at least twice the rate of placebo) were nausea, constipation and vomiting. Overall, 5 to 8 percent of the patients who received Brintellix 5 to 20 mg/day in short-term trials discontinued treatment due to an adverse reaction, the most common being nausea, compared with 4 percent of placebo-treated patients in these studies. Brintellix and other antidepressants may cause serious side effects.

In clinical studies, Brintellix had no significant effect on body weight as measured by the mean change from baseline in 6-8 week placebo-controlled studies. In the 6-month, double-blind, placebo-controlled phase of a long-term study in patients who had responded to Brintellix during the initial 12-week, open-label phase, there was no significant effect on body weight between Brintellix and placebo-treated patients. Brintellix has not been associated with any clinically significant effects on vital signs, including systolic and diastolic blood pressure and heart rate, as measured in placebo-controlled studies.

The recommended starting dose of Brintellix is 10 mg once daily without regard to meals. The dose should then be increased to 20 mg/day, as tolerated, because higher doses demonstrated better treatment effects in trials conducted in the U.S. A dose decrease down to 5 mg/day may be considered for patients who do not tolerate higher doses. The available doses provide important flexibility for physicians to help address the variability of patient needs.

Brintellix will be available as 5 mg, 10 mg and 20 mg tablets.

About Lundbeck

Lundbeck is a global pharmaceutical company highly committed to improving the quality of life of people living with brain diseases. For this purpose, Lundbeck is engaged in the entire value chain throughout research, development, production, marketing and sales of pharmaceuticals across the world. The company's products are targeted at disorders such as depression and anxiety, psychotic disorders, epilepsy, Huntington's, Alzheimer's and Parkinson's diseases. Lundbeck's pipeline consists of several mid- to late-stage development programs.

Lundbeck employs more than 5,800 people worldwide, 2,000 of whom are based in Denmark. We have employees in 57 countries, and our products are registered in more than 100 countries. We have research centres in Denmark, China and the United States and production facilities in Italy, France, Mexico, China and Denmark. Lundbeck generated revenue of approximately DKK 15 billion in 2012. For additional information, we encourage you to visit our corporate site www.lundbeck.com

About Takeda Pharmaceutical Company Limited

Located in Osaka, Japan, 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. Additional information about Takeda is available through its corporate website, www.takeda.com.

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1 WHO. Depression. Available here: http://www.who.int/mediacentre/factsheets/fs369/en/. [Last Accessed November 26, 2013]

2 Public Library of Science (PLOS). Burden of Depressive Disorders by Country, Sex, Age, and Year: Findings from the Global Burden of Disease Study 2010. Available here: http://www.plosmedicine.org/article/info%3Adoi/10.1371/journal.pmed.1001547. [Last Accessed November 26, 2013]

3 Kessler RC, Berglund, P., Demler, O., et al. (2003). The Journal of the American Medical Association; 289 (23): 3196-3105.

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