

New Study Shows Effect of Brintellix® on Sexual Functioning in MDD Patients Experiencing Treatment-Emergent Sexual Dysfunction

Takeda Pharmaceuticals Company Limited and H. Lundbeck A/S have announced results from a head-to-head study of Brintellix® (vortioxetine) versus escitalopram in patients with well-treated major depressive disorder (MDD) experiencing treatment-emergent sexual dysfunction (TESD). Results demonstrated that patients treated with Brintellix experienced a statistically significant improvement in symptoms.

In the study, 447 patients with recent major depressive episodes who had responded to selective serotonin reuptake inhibitor monotherapy but were experiencing TESD discontinued their initial treatment and were randomized to Brintellix at a dose of 10 mg/day, or escitalopram at a dose of 10 mg/day for Week 1 and 20 mg/day for Week 2 of treatment, for 8 weeks. The dose of Brintellix or escitalopram could be adjusted after Week 2, 4, or 6, as judged by the study's investigator. The primary endpoint was change from baseline to Week 8 in the Changes in Sexual Functioning Questionnaire Short-Form (CSFQ-14) total score using mixed-effects model repeated measures approach (MMRM).

The CSFQ-14 is a clinical and research instrument identifying five scales of sexual functioning and yields scores for three scales corresponding to the phases of the sexual response cycle.

Results demonstrated that patients treated with Brintellix (n = 169) experienced a statistically significant improvement, with a mean treatment difference of 2.2 points (95% confi-

New Nasal Spray May Prevent Heroin Deaths

A nasal spray application of the antiopioid drug naloxone, aimed at reducing the death toll from heroin abuse, is in its final round of clinical trials and has received Fast Track designation by the U.S. Food and Drug Administration.

Currently, naloxone is administered by injection. The nasal spray eliminates the need for needles with a ready-to-use, single-use delivery device inserted into the nose of an overdose victim. The product delivers a consistent dose that is absorbed across the nasal membranes even if the patient is not breathing.

Naloxone is the standard treatment for suspected opioid overdose and is already in use by emergency rooms and emergency medical technicians throughout the United States.

Source: "New Pharmaceutical Product to Prevent Heroin Deaths." (2014, August 7). Retrieved October 3, 2014, from <http://bit.ly/117pMQL>.



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dence interval, 0.48 to 4.02) in the CSFQ-14 total score after 8 weeks of treatment (p = 0.013; MMRM) compared to those treated with escitalopram (n = 179).

Numerically, more Brintellix-treated patients were responders (change from baseline in CSFQ-14 total score >3; odds ratio = 1.51; p = 0.06), compared with patients given escitalopram. Numerically similar responses on the Montgomery-Åsberg Depression Rating Scale total score were observed between the two groups at the end of Week 8.

These findings build on the global clinical trial program for Brintellix. The comprehensive clinical trial program evaluating the safety and efficacy of Brintellix comprised seven positive pivotal studies, including six 6- to 8-week short-term studies and one 24- to 64-week long-term maintenance study that demonstrated statistically significant improvements in overall symptoms of depression in adults with MDD.

Brintellix is an inhibitor of serotonin (5-HT) reuptake; 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. Common adverse events for Brintellix in this study were nausea, headache, and dizziness.

Source: "Results of a New Study of Brintellix® (vortioxetine) vs. Escitalopram on Sexual Functioning in Well Treated MDD Patients Experiencing Treatment-Emergent Sexual Dysfunction." (2014, June 17). Retrieved August 15, 2014, from <http://pm.to/1oODxys>. doi:10.3928/02793695-20141027-01

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