The Effect of Vortioxetine on Sexual Dysfunction in Adults With Major Depressive Disorder or Generalized Anxiety Disorder

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ABSTRACT

Introduction

Patients with major depressive disorder (MDD) and generalized anxiety disorder (GAD) often experience sexual dysfunction (SD), which negatively impacts quality of life and treatment outcomes. The objective of this study was to determine the effect of vortioxetine, an antidepressant with dual serotonin and norepinephrine reuptake inhibitor (SNRI) profile, on SD compared with placebo in patients with MDD or GAD.

Methods

A double-blind, randomized, placebo-controlled, multicenter study of 1596 patients with MDD or GAD. Patients completed a sexual dysfunction questionnaire at baseline and weeks 2, 4, 8, and 12, assessed the impact of sexual dysfunction on their daily life using the ASEX short form, and completed the Beck Depression Inventory-II (BDI-II) and Hamilton Rating Scale for Depression (HAM-D-17). The primary endpoint was the change from baseline to week 12 in ASEX mean total score. Secondary endpoints included the proportion of patients with an ASEX score of ≥4 at week 12 and change from baseline to week 12 in the BDI-II and HAM-D-17 total scores. Efficacy analyses were performed using an intention-to-treat (ITT) approach. Safety was assessed through the incidence of treatment-emergent adverse events (TEAEs) occurring during the study.

Results

Significantly more patients receiving vortioxetine had a change from baseline on any individual ASEX item compared with placebo for sexual desire (item 1), arousal (item 2), and orgasm (item 4). In addition, significantly more patients receiving vortioxetine had a change on any individual ASEX item compared with placebo for the BDI-II and HAM-D-17 total scores. Vortioxetine was generally well tolerated, with no significant differences in the incidence of TEAEs compared with placebo. Conclusions

Vortioxetine significantly improved sexual dysfunction in patients with MDD or GAD compared with placebo. Vortioxetine was generally well tolerated, with no significant differences in the incidence of TEAEs compared with placebo.