**Vyvanse® Successfully Treats Moderate to Severe Binge Eating Disorder**

Shire announced that the U.S. Food and Drug Administration approved Vyvanse® capsules, the first and only medication for the treatment of moderate to severe binge eating disorder (BED) in adults; it is shown to significantly reduce the mean number of binge days per week. Vyvanse is not indicated or recommended for weight loss or the treatment of obesity.

The efficacy of Vyvanse was demonstrated in two 12-week, randomized, double-blind, multi-center, parallel-group, placebo-controlled, dose-optimization studies in adults ages 18 to 55 (Study 1: N = 374, Study 2: N = 350) with protocol-defined moderate to severe BED (severity was defined as having at least 3 binge days per week for 2 weeks prior to the baseline visit and a Clinical Global Impression Severity score of ≥4 at baseline). The primary efficacy outcome for the two studies was defined as the change from baseline at Week 12 in the number of binge days per week. Baseline is defined as the weekly average of the number of binge days per week for the 14 days prior to the baseline visit.

Participants from both studies had a statistically significant greater reduction from baseline in mean number of binge days per week at Week 12. In the first study, Vyvanse reduced the mean number of binge days per week from 4.79 at baseline to 0.78 at study endpoint compared with 4.60 to 2.22 for the placebo. The least squares mean change from baseline in binge days per week was −3.87 and −2.51 for Vyvanse and the placebo, respectively.

Greater improvement across key secondary outcomes was also observed in those treated with Vyvanse as compared to the placebo, including a higher proportion of participants rated improved on the Clinical Global Impressions–Improvement rating scale, a higher proportion of participants had a 4-week binge cessation, and there was a greater reduction in the Yale–Brown Obsessive Compulsive Scale Modified for Binge Eating total score in both studies.

Patients with current anorexia or bulimia nervosa, current co-morbid psychiatric disorder, and cardiovascular risk factors other than obesity and smoking were excluded from the studies.


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**First and Only Orexin Receptor Antagonist for Insomnia Now Available**

Merck announced that Belsomra® is now available at pharmacies in the United States for the treatment of insomnia in adults who have difficulty falling asleep and/or staying asleep. Belsomra is the only orexin receptor antagonist approved for the treatment of insomnia in the United States. Orexin is one of the many neurotransmitters in the brain involved in promoting wakefulness, and Belsomra selectively blocks orexin receptors.

The recommended dose of Belsomra is 10 mg and taken no more than once per night and within 30 minutes of going to bed, with at least 7 hours remaining before the planned time of awakening. The total dose should not exceed 20 mg once daily.

Belsomra is contraindicated in patients with narcolepsy. Belsomra can impair daytime wakefulness.

In clinical studies, a dose-dependent increase in suicidal ideation was observed, as assessed by questionnaire. The effect of Belsomra on respiratory function should be considered.