BACKGROUND: In a previous study, dasotraline, a long-acting dopamine/norepinephrine reuptake inhibitor, demonstrated significant efficacy in the treatment of binge-eating disorder (BED). We now report an analysis from this study of the effect of dasotraline on body weight.

METHODS: Patients with a DSM-5 diagnosis of BED were randomized to 12 weeks of double-blind, flexible-dose treatment with dasotraline (4-8 mg/d) or placebo. The primary efficacy outcome was number of binge-eating days/week. Mean change in weight at week 12 was analyzed by baseline BMI category.

RESULTS: The safety population consisted of 317 patients. At baseline, the proportions of patients in each BMI category were as follows: normal (5 ± 2.7 kg/m², 25.3%), overweight (30 to <30 kg/m², 28.3%), obesity class I (30 to <35 kg/m², 26.0%), and class II (35 to <40 kg/m², 21.7%). For the overall patient sample, treatment with dasotraline significantly reduced the number of binge-eating days/week vs. placebo (5.7 ± 2.6 vs. 5.0 ± 2.4, P = 0.01); effect size (Cohen’s d) was 0.7 in patients with obesity (classes I and II) combined. Mean change in weight at week 12 was -2.0 kg (95% CI, -2.6 to -1.5) for dasotraline vs. -0.2 kg (95% CI, -0.7 to 0.2) for placebo (effect size: 0.7; NCT02564588).

CONCLUSIONS: Dasotraline 4-8 mg/d resulted in a mean change in weight of -2.0 kg vs. 0.0 kg at week 12 in patients with binge-eating disorder. The effect was consistent across all BMI categories. The most frequent weight-related adverse event was decreased appetite, reported in 19.7% of patients on dasotraline. The mean percent change in weight at Week 12 was greater for the dasotraline group vs. the placebo group (1.5% vs. -0.3%).

Table 1. Patient Demographic and Clinical Characteristics (ITT population)

| Age, years, mean (SD) | 38.7 (12.1) vs. 38.7 (12.3) |
| Female, % | 87.7 vs. 87.4 |
| White, % | 83.2 vs. 83.2 |
| Weight (kg), mean (SD) | 21.8 ± 5.2 vs. 21.7 ± 5.5 |

Figure 3. Mean Change in Weight and BMI at Week 12 (MMRM Analysis, Safety Population)

Figure 4. Mean Change in Weight by Baseline BMI Category (Observed Case, Safety Population)

Figure 5. Weight-related Adverse Events

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REFERENCES: A list of references is provided in the original publication.

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