

GLP-1 receptor agonist update – Tirzepatide for obstructive sleep apnea

• On June 21, 2024, <u>Eli Lilly presented</u> the positive results from the SURMOUNT-OSA Phase 3 trials for tirzepatide for the treatment of moderate-to-severe obstructive sleep apnea (OSA) in adults with obesity at the American Diabetes Association[®] (ADA) 84th Scientific Sessions.

— The data were simultaneously <u>published</u> in the New England Journal of Medicine (NEJM).

- Tirzepatide, under the brand name <u>Zepbound[®]</u>, is one of three glucagon-like peptide-1 (GLP-1) receptor agonists approved for chronic weight management. The other two include Novo Nordisk's <u>Saxenda[®] (liraglutide)</u> and <u>Wegovy[®] (semaglutide)</u>.
- Approximately <u>39 million adults</u> in the U.S. have OSA but only about 80% of individuals have been diagnosed.
 - There is currently no drugs FDA approved for the treatment of OSA.
- SURMOUNT-OSA included two randomized, double-blind, placebo-controlled studies in adults with moderate-to-severe OSA and obesity who were unable or unwilling to use positive airway pressure (PAP) therapy (Study 1) and those who were and planned to stay on PAP therapy during the duration of the trial (Study 2). Patients were randomized to tirzepatide or placebo for 52 weeks. The primary endpoint was the change in the apnea–hypopnea index (AHI, the number of apneas and hypopneas during an hour of sleep) from baseline.
 - At baseline, the mean AHI was 51.5 events per hour in Study 1 and 49.5 events per hour in Study 2, and the mean body mass index (BMI) was 39.1 and 38.7, respectively.
 - In Study 1, the mean change in AHI at week 52 was -25.3 events per hour with tirzepatide and -5.3 events per hour with placebo, for an estimated treatment difference of -20.0 events per hour (95% CI: -25.8, -14.2; p < 0.001).
 - In Study 2, the mean change in AHI at week 52 was −29.3 events per hour with tirzepatide and −5.5 events per hour with placebo, for an estimated treatment difference of −23.8 events per hour (95% CI: −29.6, −17.9; p < 0.001).</p>
- Zepbound is currently approved as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of:
 - 30 kg/m² or greater (obesity) or
 - 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea or cardiovascular disease).
- Lilly submitted for a label update for tirzepatide to include an indication for the treatment of moderate-to-severe OSA and obesity based on data from the SURMOUNT-OSA trials.
 - Lilly anticipates an approval decision as early as the end of this year.



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