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Effect on Body Weight of Naltrexone/Bupropion in Overweight and Obese Participants with Cardiovascular Risk Factors in a Large Randomized Double-Blind Study

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Abstract : The study assessed the effect of prolonged-release naltrexone 32 mg/bupropion 360 mg (NB) on cardiovascular (CV) events in overweight/obese participants at elevated CV risk. Participants must lose ≥ 2% body weight at 16 wks, without a sustained increase in blood pressure, to continue drug. The study was terminated early after second interim analysis with 50% of all CV events. Data on CV endpoints has been published. Current analyses focus on weight change. Intent-to-treat (ITT) population (placebo [PBO] N=4450, NB N=4455) was 54.5% female, 83.5% white, mean age 61 yrs, mean BMI 37.3 kg/m2; 85.2% had type 2 diabetes, 32.1% had CV disease, 17.4% had both. At 52 wks, ITT-LOCF analysis showed greater least squares mean percent change in weight (LSM%ΔBW) with NB (-3.1%; 95% CI -4.8, -1.4) vs PBO (-0.3%; 95% CI -1.9, 1.4). Both groups demonstrated greater weight loss while on-treatment (NB [-7.3%], PBO [-3.9%]). Odds ratios of 5% and 10% weight loss were 3.3 and 4.1 (ITT-LOCF), respectively, in NB over PBO. At 104 wks, on-treatment LSM%ΔBW was -6.3% with NB (n=1137) vs -3.5% with PBO (n=741). Major reasons for NB withdrawal were adverse events (AE, 29%) and patient decision (21%), with GI disorders being the most common. Weight loss with NB in this study, in an older population predominantly with diabetes and elevated CV risk, was somewhat lower than that observed in overweight/obese participants without diabetes and similar to participants with diabetes in Phase 3 studies.

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