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Effect on Tolerability and Adverse Events in Participants Receiving Naltrexone/Bupropion and Antidepressant Medication, Including SSRIs, in a Large Randomized Double-Blind Study

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Abstract : This 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. Only serious adverse events (SAE) and adverse events leading to discontinuation of study drug (AELDSD) were collected. The study was terminated early after second interim analysis with 50% of all CV events. Data on CV endpoints has been published. Current analyses focused on AEs in participants on antidepressants at baseline, as these individuals were excluded from Phase 3 trials. Intent-to-treat (ITT) population (placebo [PBO] N=4450, NB N=4455) was 54.5% female, 83.5% white, mean age of 61 yrs, mean BMI 37.3 kg/m2, 22.8% with a history of depression, 23.1% on antidepressants, including 15.4% on an SSRI. SAEs in participants receiving antidepressants was similar between NB (10.7%) and PBO (9.9%) and also similar to overall population (9.5% NB, 8.1% PBO). SAEs in those on SSRIs were similar, 10.1% NB and PBO 9.4%. For those on SSRIs or other antidepressants, AELDSDs were similar to overall population and were primarily GI disorders. Obesity increases the risk of developing depression. For participants taking NB and antidepressants, including SSRIs, there is a similar AE profile as the overall population and data revealed no evidence of an additional health risk with combined use.

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