Naltrexone and Bupropion Combination on Obese, Smoking Patients With Schizophrenia

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The sample of 60 evaluable subjects will have 80% power to detect a 4.5 kg differential change in weight between treatment groups, which is seen as a clinically meaningful weight change over 24 weeks, and 6 kg as the estimate of standard deviation for NB treatment based on previously published data of NB in overweight and obese but otherwise healthy people over 6 months. Although the Apovian et al. study was 56 weeks in duration, the study had a midpoint analysis at 28 weeks which showed that almost all of the weight loss had already occurred, making this data useful for our power analysis. To achieve power=0.80, with a two-tailed significance level of 0.05, 30 subjects per treatment group will be required.

All analyses will be performed on an intent-to-treat basis. Analyses will be carried using a mixed model repeated-measures analysis of variance with fixed effects of visit, treatment group, baseline score, and visit x treatment and visit x baseline score interactions and random participant-specific intercepts and slopes. Potential confounding variables will be included as covariates. The effect of treatment on 24-week change from baseline will be determined by the estimated regression coefficient of the visit x group interaction term. Differences between the treatment groups on categorical variables will be analyzed using the Fisher exact test or Chi-square

test. Independent sample t tests will be used to compare group

differences on continuous variables.