A Double-Blind, Placebo-, Bupropion- and Naltrexone-Controlled Study of the Efficacy and Safety of Three Doses of Naltrexone-Bupropion SR Combination Therapy in Obesity: Effects on Total and Visceral Adipose Tissue and Cardiovascular Risk Markers

Orexigen Therapeutics

Corresponding author: Orexigen Therapeutics, orexigen.therapeutics@cureus.com

Categories: Endocrinology/Diabetes/Metabolism

Keywords:

How to cite this poster

Abstract

Introduction: The NB-201 study (n=419 randomized) compared the efficacy and safety of bupropion SR 200 mg BID combined with naltrexone IR 16, 32 or 48 mg/day (NB16, NB32, NB48) against bupropion SR 200 mg BID, naltrexone 48 mg/day, or placebo for 24 weeks followed by a 24 week extension period. A subset of subjects also underwent DEXA and multi-slice abdominal CT scans to assess effects of therapy on abdominal and overall adipose tissue. Results: Subjects randomized to NB combination therapy groups achieved 1.5- to 2-fold greater weight loss after 24 weeks of treatment than subjects randomized to placebo or monotherapy, with weight loss among the NB groups greater than the additive effects observed for the two individual monotherapy groups. Additional weight loss with NB was also evident through 48 weeks. A subset of 75 randomized subjects had a DEXA scan and 73 randomized subjects had an abdominal CT scan at baseline and at 24 weeks. No relevant baseline differences were detected among all randomized subjects. LSmean change from baseline in total body adiposity was -14.0% for the combined NB groups, compared to -4.0%, -3.2% and -4.1% for the placebo, naltrexone- and bupropion monotherapy groups, respectively (all 3 p-values ≤ 0.01). LSmean change from baseline in visceral adiposity for the combined NB groups was -15.0%, compared to -4.6%, -0.1% and -2.3% for the placebo, naltrexone- and bupropion monotherapy groups, respectively (all 3 p-values ≤ 0.01). Beneficial effects associated with NB therapy were also observed in serum insulin, triglycerides, HDL cholesterol, plasma glucose, and waist circumference. Conclusions: The beneficial effects of NB therapy on total body weight include synergistic reduction of adipose tissue. DEXA scans indicated that the total body fat loss and the body weight loss of the combination were greater than the sum of the two component drugs demonstrating synergy of the combination. Visceral adipose tissue is associated with insulin resistance and increased cardiovascular risk. Loss of visceral adipose tissue with NB therapy was
also significantly greater than the sum of the monotherapies.