

Table 1. Data of phase III clinical trials using the naltrexone/bupropion combination.

Study	Duration	Patients	Treatment groups	Dropout	Weight loss	≥5% weight loss
COR-I ⁸	56 weeks	n = 1742	1) 32 mg NAL+360 mg BUP	49%	-6.1%	48%
		Inclusion criteria: • BMI = 30-45 Kg/m ² or • BMI = 27-45 Kg/m ² , hypertension, dyslipidaemia	2) 16 mg NAL+360 mg BUP 3) Placebo Behavioral therapy: ancillary	51% 50%	-5.0% -1.3%	39% 16%
COR-II ¹⁵	56 weeks	n = 1496	1) 32 mg NAL+360 mg BUP	46%	-6.4%	51%
		Inclusion criteria: as in COR-I Exclusion criteria: DM	2) Placebo Behavioral therapy: ancillary	46%	-1.2%	17%
COR-BMOD ¹⁴	56 weeks	n = 793	1) 32 mg NAL+360 mg BUP	42%	-9.3%	66%
		Inclusion criteria: as in COR-I Exclusion criteria: DM	2) Placebo Behavioral therapy: intensive	42%	-5.1%	43%
COR-Diabetes ¹⁶	56 weeks	n = 505	1) 32 mg NAL+360 mg BUP	48%	-5.0%	45%
		Inclusion criteria: Type 2 DM, BMI = 27-45 Kg/m ² , HbA1c = 7-10%, Glc <270 mg/dL	2) Placebo Behavioral therapy: ancillary	41%	-1.8%	19%
NB-201 ¹²	48 weeks	n = 419 Inclusion criteria: BMI = 30-40 Kg/m ² , nonsmokers, normotensive, LDL-C <190 mg/dL, TG <400 mg/dL, Glc <140 mg/dL	1) 16 mg NAL+400 mg BUP	45%	-5.4%	52%
			2) 32 mg NAL+400 mg BUP	36%	-5.4%	51%
			3) 48 mg NAL+400 mg BUP	63%	-4.3%	39%
			4) 400 mg BUP	33%	-2.7%	26%
			5) 48 mg NAL	46%	-1.2%	10%
			6) placebo	32%	-0.8%	15%
Greenway et al ¹¹	24 weeks	n = 238 Inclusion criteria: BMI = 30-40 Kg/m ²	1) 50 mg NAL+300 mg BUP	43%	-3.7%	32%
			2) 300 mg BUP+placebo	32%	-3.2%	26%
			3) 50 mg NAL+placebo	43%	-1.7%	15%
			4) Placebo+placebo	36%	-0.6%	12%

BMI: Body mass index; BUP: Bupropion; DM: Diabetes mellitus; Glc: Fasting blood glucose; HbA1c: Glycated hemoglobin; LDL-C: Low density lipoprotein-cholesterol; NAL: Naltrexone; TG: Serum triglycerides.