Rimonabant improves multiple cardiometabolic risk factors in diabetic and non-diabetic overweight/obese patients: data from RIO-Diabetes, RIO-Europe, RIO-North America and RIO-Lipids

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Purpose: To confirm the efficacy and safety of rimonabant, the first selective CB1 receptor blocker, for improving cardiometabolic risk (CMR) factors in a pooled RIO trials population.

Methods: Pooled data from the RIO-Europe, RIO-North America and RIO-Lipids trials, which included non-diabetic overweight/obese patients with/without comorbidities,
and data from RIO-Diabetes, a trial including overweight/obese patients with type 2 diabetes, were analysed. Patients (on a mild hypocaloric diet) were randomised to placebo, or rimonabant 5 or 20 mg/day.

Results: Changes in CMR factors over 1 year for placebo and rimonabant 20 mg/day (RIM 20) are shown for both populations (table); for specific CMR factors approximately 50% of improvements were beyond the effect of weight loss alone. In all RIO studies, rimonabant had a favourable safety profile.

Conclusion: Rimonabant 20 mg/day significantly improved multiple CMR factors in diabetic as well as non-diabetic overweight/obese patients, and was generally well tolerated.

Parameter	Mean change from baseline at 1 year			
	Non-diabetic patients		Diabetic patients	
	Placebo (ITT/) (completers)	RIM 20 (ITT/) (completers)	Placebo (ITT/) (completers)	RIM 20 (ITT/) (completers)
N	1254/701	2164/1257	348/231	339/229
Body weight (kg)	-1.6/-2.8	-6.5[†]/-8.6[†]	-1.4/-1.9	-5.3[†]/-6.1[†]
Waist circumference (cm)	-2.5/-3.9	-6.4[†]/-8.5[†]	-1.9/-2.4	-5.2[†]/-6.0[†]
HDL-cholesterol (% change)	8.9/11.2	16.4[†]/20.6[†]	7.1/8.4	15.4[†]/18.2[†]
Triglycerides (% change)	5.8/2.6	-6.9[†]/-12.0[†]	7.3/5.1	-9.1[†]/-11.7[†]
Fasting plasma glucose (mmol/L)[1]	0.02/0.02	-0.02[*]/-0.04[*]	0.33/0.42	-0.64[†]/-0.81[†]
Fasting plasma insulin (μIU/mL)	1.9/0.9	-0.6[†]/-1.3[†]	0.4/0.1	-0.7/-1.3
Systolic BP (mmHg)	-0.1/-0.7	-0.8/-1.6	1.6/1.8	-0.8[*]/-0.7[*]
C-reactive protein (mg/L)[2]	-0.4/-0.7	-1.0[*]/-1.3[‡]	-0.1/-0.1	-0.6[‡]/-0.7[*]

P [*]<0.05, [‡]<0.01, [†]<0.001 vs placebo. ITT, intention-to-treat. (1) In RIO-Diabetes, 1-year change in HbA1c was 0.1% vs -0.6% for placebo vs RIM 20 (P<0.001) (ITT) (for completers: 0.1% vs -0.7%, respectively; P<0.001) (2) RIO-Lipids only.