

RIMONABANT IMPROVES HEALTH-RELATED QUALITY OF LIFE IN OVERWEIGHT/OBESE PATIENTS WITH TYPE 2 DIABETES: RIO-DIABETES STUDY

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OBJECTIVES: To evaluate the impact of the first selective cannabinoid type 1 (CB1) receptor blocker, rimonabant, developed for the management of cardiometabolic risk factors, on health related quality of life (HRQOL) in overweight/obese patients with type 2 diabetes. **METHODS:** A total of 1045 patients with type 2 diabetes were randomized in a double-blind

trial and received either rimonabant 5mg, 20 mg or placebo. Patients completed the Impact of Weight on Quality of Life-Lite (IWQOL-Lite), a validated 31-item questionnaire specifically designed for HRQOL assessment in obesity, and reported days missed from work at baseline and every 3-months up to 1 year.

Analyses were performed on mean score changes from baseline to 1 year in the ITT population. Clinical meaningfulness was assessed using the Effect Size (ES) method, which is a measure of change over time that takes into account the variability within the sample at baseline. **RESULTS:** At 1 year, patients administered rimonabant 20 mg once daily (N = 339) reported significantly greater improvement ($p < 0.001$, and $p = 0.03$ for Work) in IWQOL-Lite total score and 3 out of 5 domains (Physical Function, Self-esteem and Work) than patients in the placebo group (N = 348) (no significant change in Sexual Life and Public Distress). These improvements were clinically meaningful ($ES > 0.2$). Also, there was a trend to fewer days missed from work reported by patients on rimonabant 20 mg (720 days) compared with those on placebo (1242 days) over the study period ($p = 0.2$ based on the number of patients with at least 1 day missed from work). **CONCLUSIONS:** HRQOL results showed both a statistically significant and clinically meaningful improvement in total score and also several domains (Physical Function, Self-esteem and Work) of the IWQOL-Lite questionnaire, with rimonabant versus placebo after a once daily administration of 20 mg rimonabant in this population of overweight/obese patients with diabetes.