

## **P-59 - SHIFTING THE PARADIGM: REDUCTION OF ALCOHOL CONSUMPTION IN ALCOHOL DEPENDENT PATIENTS - A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF NALMEFENE, AS-NEEDED USE**

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**Introduction:** Current treatments for alcohol dependence, aiming to keep patients abstinent, have shown limited treatment and success rates. Reduction of alcohol consumption is increasingly recognised as a valid and needed option that should be an integrated part of the management of alcohol-dependent patients.

**Objectives:** The main objective was to evaluate the efficacy of as-needed use of nalmefene 18mg (base) *versus* placebo in reducing the monthly number of heavy drinking days (HDDs) and the monthly total alcohol consumption (TAC; g/day) over 24 weeks in alcohol-dependent patients.

**Methods:** Drinking measures were derived from daily drinking estimates collected with the Timeline Followback method. Safety and additional efficacy data were collected throughout the study.

**Results:** A total of 604 patients (mean age 51.6±9.6 years, 67% men) were randomised (298 to placebo and 306 to nalmefene). There was a significantly superior effect (mixed model repeated measures) of nalmefene compared to placebo in reducing the number of HDDs (-2.3±0.8 [95% CI -3.8; -0.8]; p=0.002) and TAC (-11.0±3.0 [95% CI -16.8; -5.1]; p< 0.001). Improvements in Clinical Global Impression - Global Improvement and Severity of Illness scores and reductions in liver enzymes gamma-glutamyltransferase and alanine aminotransferase from baseline were statistically significantly larger in the nalmefene group compared to placebo at week 24. Adverse events (generally transient; most were mild or moderate) and withdrawals were more common with nalmefene than placebo.

**Conclusions:** Nalmefene was efficacious in reducing alcohol consumption. Nalmefene was safe and well tolerated and dosing on an as-needed basis was feasible.