CLINICAL RELEVANCE OF AS-NEEDED TREATMENT WITH NALMEFENE IN ALCOHOL DEPENDENT PATIENTS

H. Aubin[1], J. Reimer[2], D. Nutt[3], L. Torup[4], C. FranÁois[5], J. Chick[6]

[1]Psychiatry and Addiction Science Department, Univerité Hospital Paul Brousse, Villejuif, France ; [2]Centre for Interdisciplinary Addiction Research, Hamburg University, Hamburg, Germany ; [3]Department of Medicine, Imperial College, London, United Kingdom ; [4]Addictive Behaviors, H. Lundbeck A/S, Valby, Denmark ; [5]Pharmacoeconomics, H. Lundbeck A/S, Issy les Moulineaux, France ; [6]Health Sciences, Queen Margaret University, Edinburgh, United Kingdom

Introduction: The opioid system modulator nalmefeneis the first pharmacological therapy approved in the European Union for reduction of alcohol consumption.

Objectives: To evaluate the clinical relevance of the reduction of alcohol consumption in patients with at least high drinking risk level at screening and randomisation from the two, identically designed, randomised controlled 6-month studies ESENSE1 (NCT00811720) and ESENSE2 (NCT00812461) of nalmefene versus placebo.

Methods: Study medication was taken as-needed. All patients received a motivational and adherence-enhancing intervention (BRENDA). Response criteria were based on alcohol consumption at month 6 and Clinical Global Impression – Severity of Illness/Improvement (CGI-S/I), Short Form Health Survey version 2 (SF-36) mental component summary(MCS) scores at week 24. Clinical relevance was also studied using the Drinker Inventory of Consequences (DrInC), Alcohol Dependence Scale (ADS), and liver function variables.

Results: Pooled study population: 667 patients (placebo N=332; nalmefene N=335). The proportion of responders was higher in the nalmefene group than in the placebo group with odds ratios for response consistently significantly (p<0.05) in favour of nalmefene.The difference in the proportions of responders translated to numbers-needed-to-treat ranging from 6 to 10. Significant differences to placebo (p<0.05) in the SF-36 MCS and physical component summary score, ADS, DrInC, CGI-I/S and liver enzymes further supported the clinical relevance of the treatment effect.

Conclusions: In view of the immense alcohol-related burden to society, the harm to the individual and the large treatment gap partly due to a reluctance to engage in abstinence, the effect of nalmefene is clearly clinically relevant.

Author Keywords: alcohol dependence, reduction, nalmefene, randomised controlled trial, clinical relevance