

## AS-NEEDED USE OF NALMEFENE IN THE TREATMENT OF ALCOHOL DEPENDENCE

J. Sinclair<sup>1</sup>, P. Batel<sup>2</sup>, F. Kiefer<sup>3</sup>, J. Chick<sup>4</sup>, P. Sørensen<sup>5</sup>, A. Gual<sup>6</sup>

<sup>1</sup>Department of Psychiatry, University of Southampton, Southampton, UK, <sup>2</sup>AP-HP, Hôpital Beaujon, Groupe Hôpitaux Universitaires Nord Val-de-Seine, Clichy, France, <sup>3</sup>Department of Addictive Behaviour and Addiction Medicine, Central Institute of Mental Health, University of Heidelberg, Mannheim, Germany, <sup>4</sup>Health Sciences, Queen Margaret University, Edinburgh, UK, <sup>5</sup>H. Lundbeck A/S, Valby, Denmark, <sup>6</sup>Department of Psychiatry, Alcohol Unit, Institute of Neurosciences, Hospital Clinic, Barcelona, Spain

**Introduction:** In the phase 3 programme on nalmefene for reduction of alcohol consumption in alcohol dependent patients, an as-needed dosing regimen was used. Patients were instructed to take one tablet on each day they perceived a risk of drinking alcohol, preferably 1 to 2 hours prior to the anticipated time of drinking. Tablets could be taken up to once daily. As-needed use is a patient-centered approach engaging patients in active and responsible management of their illness. It should be seen as an integral part of disease management, increasing awareness of drinking amount and patterns, facilitating identification of at-risk situations.

**Objectives:** Explore the feasibility of as-needed use of nalmefene in alcohol dependence.

**Methods:** The Timeline Follow-back was used to obtain estimates of daily drinking and to record daily medication intake. Pooled data (treated patients: nalmefene=643; placebo=633) from the two randomised controlled 6 month studies (ESENSE 1 [NCT00811720] and ESENSE 2 [NCT00812461]) was used. Adherence was defined as medication intake and alcohol consumption, or no alcohol consumption (with or without medication intake).

**Results:** Nalmefene was taken on approximately half of the study days; placebo was taken more often than nalmefene. In each treatment group, medication intake varied according to patients' needs as intake correlated with baseline drinking pattern. 68% of the nalmefene treated patients (78% of the study completers) adhered to the as-needed treatment regimen on at least 80% of the study days.

**Conclusions:** These results demonstrate that patients understand, accept, and adhered to the as-needed treatment regimen.