A RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED EFFICACY STUDY OF HIGH-DOSE BACLOFEN IN ALCOHOL DEPENDENT PATIENTS: THE ALPADIR STUDY

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The objective of this study was to assess the efficacy and safety of baclofen at the target dose of 180 mg/day for the maintenance of abstinence (primary endpoint) and the reduction of alcohol consumption (secondary endpoint) in alcohol dependent patients. The main inclusion criteria were: adult men or non-pregnant, non-breastfeeding women, with a diagnosis of alcohol dependence according to DSM-IV, who had experienced at least one previous abstinence attempt, and had been fully abstinent for 3 to 14 days before inclusion and randomization. The main exclusion criteria were: need for a prolonged residential treatment after detoxification, need for a heavy psychosocial follow-up, epilepsy or history of epilepsy, concomitant treatment with psychotropic medications except antidepressants at stable dose for 2 months, diazepam and oxazepam, severe psychiatric condition (schizophrenia and bipolar disorder), suicidal risk or history of suicide, other current dependence excepted nicotine. 320 patients (158 baclofen and 162 placebo) were randomized after alcohol detoxification. After a 7-week titration, the maintenance dose was provided for 17 weeks, then tapered and stopped in 2 weeks. During titration and maintenance periods, the dose could be reduced in case of persistent sedation/somnolence; an attempt to return to the higher dose could be tried after a 3-day period of stability and satisfactory tolerance. Patients who did not reach the target dose of 180 mg/day participated in the study at their maximum tolerated dose. During all the study period, patients reported daily their alcohol consumption (number of standard drinks) and study treatment intake on a paper diary. The primary outcome measure was the rate of abstinent patients

during twenty weeks of treatment from Day 29 (start of the 5th week) to Day 168 (end of the maintenance period). A grace period was authorized from Day1 (start of study treatment) to Day 28. Efficacy and safety results will be presented during the session.

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