P-131 - LONG TERM STUDY OF PREGABALIN FOR THE TREATMENT OF GENERALIZED ANXIETY DISORDER: A 1 YEAR OPEN-LABEL EXTENSION

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Introduction: Short-term clinical trials have demonstrated the efficacy and safety of pregabalin for the treatment of generalized anxiety disorder (GAD).
Objectives and aims: This study examines the long-term safety and efficacy of pregabalin (150-600 mg/day) in patients diagnosed with GAD.
Methods: Patients completing two short-term, double-blind efficacy trials of pregabalin for the treatment of GAD (n=329) were enrolled in this 1-year, non-randomized, open-label safety extension study. Disease severity was assessed at baseline, week 27, and week 52 using the Clinical Global Impression of Severity (CGI-S) score (7-point scale). Patients were characterized as “responders” or “non-responders” based on CGI-S scores of ≤2 an >2, respectively. Safety and tolerability were also assessed.
Results: Patients were predominately white (98.5%), female, (67.8%) and had a mean (SD) age of 55 (17) years. Mean (SD) CGI-S scores at baseline (n=329) and endpoint (n=319) were 3.55 (1.07) and 2.58 (1.18), respectively, for all patients. One hundred fifty-four (46.8%) patients were characterized as CGI-S responders at endpoint compared to 50 (15.2%) patients at baseline. The number of patients shifting from a non-responder to a responder was 122 (37.1%). Conversely, the number of patients shifting from a responder to a non-responder was 14 (4.3%).
Conclusion: Pregabalin's anxiolytic efficacy was maintained over the 1 year study period. The severity of anxiety symptoms decreased with extended pregabalin treatment, evident by decreased CGI-S score and an increased number of CGI-S responders at endpoint compared to baseline.This study was funded by Pfizer Inc.

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