

EUROPEAN MANIA IN BIPOLAR LONGITUDINAL EVALUATION OF MEDICATION (EMBLEM) STUDY: RESULTS OF THE ACUTE 12-WEEK PHASE IN ITALY BY REGIONAL LOCATION (NORTH, CENTRE AND SOUTH)

Rossi Andrea 1, Barraco Alessandra 1, Goetz Iris 2, Mancini Michele 1 for the Italian EMBLEM study group

1 Eli Lilly Italia S.p.A.

2 Eli Lilly and Company, Windlesham, UK

EMBLEM is an European observational study aimed at assessing the effects of the start or the changes to olanzapine or non-olanzapine medication for the treatment of mania in bipolar disorder patients with a manic or mixed episode. The results of the 3-month acute phase of the study in Northern (N), Central (C) and Southern (S) Italy are herein presented.

A total number of 557 (N = 203, C = 107, S = 247) adult in- or out-patients were evaluated in 56 sites. The acute phase of the study included 5 visits (baseline and weeks 1, 2, 3, 6 and 12), in which the prescribed and concomitant medications, and the clinical and functional status, were recorded. Of examined patients, 189, 92 and 240 in N, C and S, respectively, completed the acute phase. In-patients in N, C and S were 97 (47.8%), 48 (44.9%) and 41 (16.6%) at baseline, and 11 (5.4%), 4 (3.7%) and 4 (1.6%), respectively, at month 3. The mean (\pm SD) mania score of the CGI-BP at baseline and month 3 were 4.6 ± 1.0 and 2.0 ± 1.1 in N, 4.7 ± 0.9 and 2.4 ± 1.1 in C, and 4.2 ± 0.7 and 2.6 ± 1.1 in S, respectively. No substantial changes from baseline in any geographic area were observed for scores of CGI-BP depression, while similar decreases from baseline were found for scores of hallucinations/delusions. Improvement (first decrease ≤ 2 points in the overall CGI-BP at any time) was observed in 58.1% of patients in N, and in 44.9% in both C and S; the corresponding rates of worsening (first increase of at least one point to a minimum of 3 in the overall CGI-BP at any time) were 29.6%, 17.8% and 24.3, respectively. The total score of the 5-item Hamilton Depression Scale at baseline and month 3 was 2.2 ± 2.4 and 1.5 ± 1.9 in N, 3.1 ± 2.6 and 2.6 ± 2.2 in C, and 3.7 ± 2.4 and 2.1 ± 2.1 in S, respectively. Marked and similar decreases in all geographic areas were found for total and subscale scores of the Young Mania Rating Scale. Rates of compliant patients were $> 80\%$ in all areas. The mean doses of olanzapine in monotherapy were 13.2 mg in N, 13.6 mg in C and 11.2 mg in S, while doses given in combined therapies were 13.7, 15.3 and 12.3 mg, respectively. Differences between the 3 examined geographic areas were found in mean dosages of agents given in monotherapy (highest mean dose of haloperidol and lowest for valproate in C), and in combined therapy (highest mean dose of haloperidol in N and valproate in C, and lowest mean dose of lamotrigine in S). Although an overall general improvement of symptoms of mania was observed, the analysis by geographic area (Northern, Central and Southern Italy) showed some differences in prescription and outcome.