Reviewer's report

Title: The Management of Bipolar Mania: a national survey of Baseline data from the EMBLEM study in Italy

Version: 2 Date: 14 December 2006

Reviewer: Michael J Ostacher

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General
This is an interesting observational study of the treatment of mania in different settings in Italy. It can provide readers from other countries with a view of the demographics of patients treated for mania, and includes several interesting findings -- a relatively late age of onset of bipolar disorder, a low rate of past suicide attempts, and a low lifetime rate of alcohol and other drug problems. It is also interesting that even in this European cohort, BMI is in the overweight range on average (suggesting a high proportion of patients are likely obese.) It is not an epidemiological study, however, and has significant limitations in terms of its generalizability.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

The initial study design of the European Mania in Bipolar Longitudinal Evaluation of Medication (EMBLEM) study should be disclosed: two cohorts of patients were recruited, one in which the baseline treatment was changed to olanzapine and another in which the baseline treatment was changed to another drug.

It is not surprising that the rate of olanzapine use is so high, as this is an Eli Lilly funded study in which one of the stated purposes of the study was to follow patients started on olanzapine. By not stating so, the authors imply that this high rate of olanzapine prescribing is random, but it is clearly not. To quote from another publication of data from the EMBLEM study "Investigators were asked, but not required, to include 50% of patients into the study who were initiated or changed to olanzapine and 50% of patients initiated or changed to non-olanzapine treatment." (Touloumis C, et. al. Annals of General Psychiatry 2006, 5(Suppl 1):S197) For this reason, data regarding what medications the patients were switched to should be either removed from the manuscript or described in the methods section as part of the study protocol.

Because the treating psychiatrists were specifically asked to recruit half the subjects to be prescribed olanzapine and half to be prescribed other compounds, the choice of subjects for participation was not random. Half the sample are patients whose psychiatrists believed would be appropriate for treatment with olanzapine. This should be explicitly stated as a limitation of the study.

It is not a limitation of the study that the patients are heterogeneous; bipolar patients are a heterogeneous group. This is also not a "naturalistic observational study". It is an observational study, but not naturalistic, since the treating psychiatrist were asked to include specific proportions of patients.

It is not clear that CGI-BP be reliably used to rate the past year’s symptoms; the retrospective diagnosis of past year’s symptoms should be stated as a limitation of the study.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)

Data on obesity rates (proportion with BMI > or = to 30) would be interesting to include.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions
Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:

Research support from Pfizer. Speaker honoraria from AstraZeneca, Bristol Myers Squibb, Forest Pharmaceuticals, Glaxo SmithKline, Janssen Pharmaceutica, Pfizer.