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OBJECTIVE: To evaluate the effect of long-term AOM 400 maintenance treatment on manic and depressive symptoms in BP-I patients from the open-label, long term safety study.

METHODS: Manic and depressive symptoms were assessed post-hoc by analysis of change from study entry in the Young-Mania Rating Scale (YMRS) and Montgomery-Åsberg Depression Rating Scale (MADRS) total scores and line item scores. The mean changes from baseline at last visit in YMRS and MADRS total scores, and single items were calculated using descriptive statistics, using last observation carried forward for total scores and observed cases for single items.

RESULTS: A total of 464 patients entered the maintenance phase: 379 were de novo and 85 were rollover patients who completed the double-blind, placebo-controlled withdrawal study. Overall, 63% (291/464) completed 52 weeks of open-label treatment. Mean YMRS and MADRS total scores were minimally changed from baseline (YMRS: 2.31, endpoint change -0.30; MADRS: 3.23, endpoint change +1.24) across the study in the total population.

CONCLUSION: Patients entering an open-label safety study with stable manic and depressive symptoms maintained stability in both types of symptoms, as shown by minimal mean changes from baseline in YMRS and MADRS scores, suggesting that treatment with AOM 400 is effective in preventing re-emergence of both manic and depressive symptoms.

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Symptom Stability in de Novo and Rollover Patients with Bipolar I Disorder Receiving Aripiprazole Once-monthly in a 52-Week, Open-label Study

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ABSTRACT: Introduction: Long-term maintenance treatment is essential in management of bipolar I disorder (BP-I) to achieve mood stability, prevent recurrence of mood episodes and improve functioning. Aripiprazole once-monthly 400 mg (AOM 400) is a long-acting formulation of aripiprazole for maintenance treatment of BP-I. In a double-blind, placebo-controlled, randomized withdrawal study in adult patients with BP-I after a manic episode (NCT01567527), AOM 400 delayed time to and reduced rate of recurrence of mood episodes and was safe and well tolerated (1). In an open-label, long-term safety study (NCT01710709), AOM 400 was safe and effective as long-term maintenance treatment (2).

OBJECTIVE: To evaluate the effect of long-term AOM 400 maintenance treatment on manic and depressive symptoms in BP-I patients from the open-label, long term safety study.

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