A Double-Blind, Randomized, Placebo Controlled Trial of Ramelteon for the Treatment of Insomnia and Mood Stability in Patients with Euthymic Bipolar Disorder (Poster)

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Purpose
Abnormalities in circadian rhythms are prominent features of bipolar I disorder (BDP). Literature suggests that disrupted 24-hour sleep-wake circadian rhythms are associated with an increased risk of relapse in bipolar disorder. Bipolar patients have shorter, and more variable, circadian activity patterns even when not acutely ill. It is proposed that normalizing the circadian rhythm pattern of bipolar patients will improve their sleep; and consequently, also lead to fewer mood exacerbations. Ramelteon offers a mechanism to re-synchronize the suprachiasmatic nucleus. The administration of ramelteon for bipolar patients will improve sleep and will cause fewer mood exacerbations.

Methods
This single-site, double-blind, randomized, placebo-controlled trial was conducted to examine the efficacy of ramelteon in the treatment of insomnia and mood stability in patients with euthymic bipolar disorder. Patients with bipolar disorder have shorter, and more variable, circadian activity patterns even when not acutely ill. It is proposed that normalizing the circadian rhythm pattern of bipolar patients will improve their sleep; and consequently, also lead to fewer mood exacerbations. Ramelteon offers a mechanism to re-synchronize the suprachiasmatic nucleus. The administration of ramelteon for bipolar patients will improve sleep and will cause fewer mood exacerbations.

Results
90 individuals signed informed consent and 83 participants were enrolled in the study and were randomized to receive ramelteon (n = 42) or placebo (n = 41). There was no evidence of group differences on background variables; nor were there differences between groups on any of the measures used to monitor disease progression, including PSQI, YMSM, MADRS, or CGI. Overall, there were 40 patients who relapsed (48.2%). The results of the Cox regression analyses indicated that the ramelteon group (Odds Ratio 0.48, p = .024) was significantly less likely to relapse over the course of the 24 week study than patients in the placebo group. Kaplan-Meier curves also indicated significantly longer median survival times in the drug group (Mdn = 188 days since baseline) versus the placebo group (Mdn = 84 days since baseline) X2(1) = 5.33, p = .02. There were no serious adverse events in this study.

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