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Supplementary Material

Article Title: Efficacy and Safety of Quetiapine in Children and Adolescents With Mania Associated With Bipolar I Disorder: A 3-Week, Double-Blind, Placebo-Controlled Trial

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Supplementary eAppendix 1. The Trial 149 Study Investigators

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Supplementary eAppendix 2. Details of the safety analyses

Categorical worsening in Simpson-Angus Scale (SAS), Barnes Akathisia Rating Scale (BARS), and Abnormal Involuntary Movement Scale (AIMS) scores was investigated using generalized estimating equation (GEE) analysis. GEE analysis was used as assumptions of normality did not hold for SAS and AIMS total scores or the BARS global score. Covariates included age stratum, treatment, visit, visit-by-treatment interaction, and baseline score. ANCOVA was used to assess change from baseline to Day 21 in prolactin concentration over time. Rates of anticholinergic medication use in the quetiapine and placebo groups were compared using logistic regression. Suicidality analyses were conducted post hoc utilizing standardized classifications similar to those in the Columbia Suicidality Classification Project.[1] Remaining safety analyses used descriptive statistics.

REFERENCE

1. Posner K, Oquendo MA, Gould M, et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *Am J Psychiatry*. 2007;164(7):1035–1043.

Supplementary eTable 1. Key Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Age 10 to 17 years • Male or female • BP-I mania (DSM-IV-TR, confirmed by K-SADS-PL) • YMRS total score ≥ 20 at screening and randomization • Confirmed absence of pregnancy	• DSM-IV diagnosis of Axis I disorder other than bipolar I disorder or ADHD • Premorbid intelligence quotient <70 or diagnosis of mental retardation • History of serious suicide attempt, at current suicide risk, or at serious homicide risk • Psychotic symptoms related to medication or substance abuse or judged to be direct physiological consequence of a medical treatment or condition • Current manic episodes that resulted from psychostimulant or antidepressant medication • TSH concentration more than 10% above the upper limit of the normal range • Laboratory test results outside the normal reference range • Unstable diabetes mellitus with a baseline glycosylated hemoglobin (HbA1c) ≥8.5 • A hospital admission for diabetes or related illness in the past 3 months • Other medical conditions that were unstable or may have affected or been affected by the study medication and pregnancy or lactation • Concurrent cognitive-behavioral therapy initiated within 6 weeks prior to randomization

ADHD, attention deficit hyperactivity disorder; DSM-IV-TR, Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition, text revision; K-SADS-PL, Schedule for Affective Disorders and Schizophrenia for School-Age Children—Present and Lifetime Version; TSH, thyroid-stimulating hormone.