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LINE ITEM ANALYSIS IN PAEDIATRIC PATIENTS WITH BIPOLAR I DISORDER TREATED WITH ARIPIPRAZOLE

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Introduction: Aripiprazole has demonstrated efficacy for the treatment of paediatric patients (10-17 years) with a manic or mixed episode associated with bipolar I disorder in a clinical trial that utilised the Young Mania Rating Scale (YMRS) Total score as the primary outcome measure.

Objectives/aim: This analysis evaluated the profile of discrete symptom response using the YMRS and other measures.

Methods: Post-hoc analysis of individual items of the YMRS and the parent or subject version of the General Behaviour Inventory (GBI) Mania and Depression scales using data from a 4-week, double-blind, randomised trial that compared aripiprazole (10 or 30 mg/day, n=197) with placebo (n=99).

Results: In total, 296 patients were randomised; 80% completed the study. Significant decreases at Week 4 ($p < 0.05$) were seen in eight YMRS items: elevated mood, increased motor activity/energy, need for sleep, irritability, speech (rate and amount), language/thought disorder, abnormal thought content and disruptive/aggressive behaviour. For the GBI, effect sizes for parent-reported mania items were medium to large (for example, 0.41 for 'depressed but high energy' to 0.78 for 'rage combined with unusually happy') but were consistently small on subject self-reported items of mania and depression and, for the overall scale, had the poorest agreement with clinician ratings.

Conclusions: Aripiprazole demonstrated improvements in some of the more troublesome symptoms of paediatric patients with bipolar I disorder experiencing an acute manic or mixed episode. Of note, irritability and aggression showed large treatment effects on both clinician and parent-reported measures, but less so for subject-reported measures.

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