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SAFETY AND TOLERABILITY OF ARIPIPRAZOLE IN THE TREATMENT OF IRRITABILITY ASSOCIATED WITH AUTISTIC DISORDER IN PEDIATRIC PATIENTS: RESULTS FROM A 52-WEEK OPEN-LABEL STUDY

W. Landsberg[1], J.-Y. Loze[2], G. Lau[3], G. Manos[4], R. McQuade[5], L. Kamen[6], R. Marcus[6], R. Mankoski[7]

[1]Bristol-Myers Squibb Co., [2]Otsuka Pharmaceutical, Paris, France, [3]Otsuka America Pharmaceuticals, Inc., Princeton, NJ, [4]Bristol-Myers Squibb Co., Wallingford, CT, [5]Otsuka Pharmaceutical Development and Commercialization Inc., Princeton, NJ, [6]Bristol-Myers Squibb, Wallingford, CT, [7]Bristol-Myers Squibb, Plainsboro, NJ, USA

Objective: Evaluate the time-course, severity and resolution patterns of adverse events (AEs) occurring with long-term aripiprazole treatment for irritability associated with autistic disorder.

Methods: Participants were treated with aripiprazole in a 52-week, open-label, flexibly dosed (2-15 mg/day) study. Subjects had either completed one of two 8-week randomised trials or were de novo. AEs with an incidence of ≥10% were evaluated by incidence, peak first onset, severity, percent resolved and time to resolution.

Results: A total of 330 subjects entered open-label treatment; 199 completed 52 weeks. Mean dose for the population stabilised at around 10 mg/day after approximately 4 months. Thirteen AEs had an incidence of ≥10%; most were mild or moderate in severity. Vomiting, diarrhoea and headache had an early first onset and tended to resolve fairly quickly. Sedation, fatigue and insomnia also appeared early and resolved in a majority of cases, but not as quickly. Increased appetite appeared early (followed by increased weight) and fewer weight-related AEs resolved. More than half of the subjects increased their weight by at least one percentile category rank; nevertheless, only a small proportion of subjects with normal baseline metabolic or glucose measures had a treatment-emergent, clinically relevant laboratory abnormality. Nasopharyngitis, upper respiratory infection, cough, nasal congestion and pyrexia all had peak onset at variable times during the study, resolving in nearly all cases, with short time to resolution.

Conclusion: AEs were mostly mild or moderate and of variable duration. Increased weight was observed.

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