AAN 69th ANNUAL MEETING ABSTRACT

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EMBARGOED FOR RELEASE UNTIL 4 P.M. ET, MONDAY, FEBRUARY 27, 2017

Abstract Title: Extrapolation of Efficacy Data from Adults with Primary Generalized Tonic-clonic Seizures (PGTC) to Pediatric Patients: A Meta-analysis of Published Clinical Trials

Press Release Title: Good News for Kids with Epilepsy

Objective: To evaluate feasibility of using antiepileptic drug (AED) efficacy data from published trials conducted in adults and children to extrapolate efficacy in pediatric patients with PGTC seizures.

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Background: Availability of new AEDs for pediatric patients has been delayed due to the challenges of conducting clinical trials in children. The feasibility of extrapolation of adjunctive efficacy results for partial-onset seizures has been shown from adult to pediatric populations when the disease course and pharmacokinetics of drug effects are comparable between populations (Pellock et al. Neurology 2012;79:1482–1489). In response to a request from the Pediatric Committee of the European Medicines Agency, our study explored the feasibility of extrapolating AED efficacy data from adults to pediatric patients with PGTC seizures.

Design/Methods: Electronic searches in EMBASE®, Medline® and the Cochrane Central Register of Controlled Trials were conducted for randomized, placebo-controlled clinical trials of adjunctive AED treatment for PGTC seizures in adults and children published from 1970 to 2015. Outcome data, expressed as median percent reduction in PGTC seizure frequency and ≥50% responder rate, were extracted from eligible trials for adult and pediatric patients receiving adjunctive AEDs or placebo, and used to determine the relative strength of baseline-subtracted efficacy measures.

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Results: Seven published trials of AED adjunctive therapy for PGTC seizures were eligible for quantitative analysis. Changes in efficacy measures were similar in adults and children with PGTC seizures and were not age-dependent. The 95% confidence intervals for the standardized mean difference in median percent reduction of seizure frequency and estimated risk ratios in ≥50% responder rate were consistently in favor of the AED treatment and comparable between adult and pediatric groups.

Conclusions: Across a likely spectrum of syndromes with generalized seizures, the effect of adjunctive AED treatment on PGTC seizures appears similar between adults and children.

Study Supported by: Eisai Inc.