AAN 67th ANNUAL MEETING ABSTRACT

Media Contacts:
Rachel Seroka, rseroka@aan.com, (612) 928-6129
Michelle Uher, muher@aan.com, (612) 928-6120

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Abstract Title: Epidiolex (Cannabidiol) in Treatment Resistant Epilepsy

Press Release Title: Medical Marijuana Liquid Extract May Bring Hope for Children with Severe Epilepsy

Objective: Ten centers have independent FDA approved open-label Expanded Access Programs and have treated children and young adults with treatment-resistant epilepsies with pure CBD.

Author(s): Orrin Devinsky, MD, FAAN; Joseph Sullivan; Daniel Friedman, MD; Elizabeth Thiele, MD; Eric Marsh, MD, PhD; Linda Laux, MD; Ian Miller, MD; Robert Flamini, MD; Angus Wilfong, MD; Francis Filloux, MD; Matthew Wong, MD; Nicole Tilton; Patricia Bruno; Judith Bluvstein, MD; Maria Roberta Cilio, MD

Background: Cannabidiol (CBD) is a component of Cannabis sativa with anticonvulsant activity in pre-clinical models of epilepsy, independent of activity at known endogenous cannabinoid receptors.

Design/Methods: Data has been collected on demographics, seizure counts, and safety through case report forms and tabulated in this series of open-label trials. Eligibility was determined and documented in protocols specific to each site after FDA and IRB review. Seizures were recorded as convulsive (countable) or non-convulsive. Atonic seizures were also specifically recorded. CBD (supplied by GW Pharmaceuticals) was given as a liquid and daily dose titrated up to 25mg/kg.

Results: Data were collected on 213 patients with treatment-resistant epilepsies for safety evaluation. 123 patients had at least 12 weeks continuous exposure and were included in efficacy calculations. Etiologies included Dravet and Lennox-Gastaut (LGS) syndromes as well as over 10 other conditions. Total convulsive and non-convulsive seizures showed a median percent reduction from baseline of -46% at week 12. Convulsive seizure frequency among Dravet patients treated for at least 12 weeks (N=23) was reduced by 51% at week 12. In patients with LGS treated for 12 weeks (N=10), atonic seizure frequency was reduced by a median -52% at week12. Adverse events >10% were somnolence (21%), diarrhea (17%), fatigue (17%), and decreased appetite (16%). Nine patients (4%) discontinued for AEs.

Conclusions: CBD showed reductions in seizure frequency across multiple drug-resistant epilepsy syndromes and seizure types and was generally well tolerated in this open-label cohort. Controlled trials are indicated to characterize efficacy and safety.

Study Supported by: GW Pharmaceuticals.