New Reports of Epidiolex® Efficacy and Safety Presented at the American Epilepsy Society Annual Meeting

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SEATTLE, December 8, 2014 – Anecdotal experience and emerging data suggest that CBD might be a promising treatment for the control of seizures and systematic investigation is underway. Three studies exploring the efficacy and safety in the development of a purified and formulated form of cannabis called Epidiolex will be presented at the American Epilepsy Society’s (AES) 68th Annual Meeting. These three studies are precursor studies to a randomized clinical trial.

In the first study (Poster #3.303) twenty-three patients with treatment-resistant epilepsies, especially Dravet Syndrome, with an average age of 10, were enrolled in two epilepsy centers at New York University and the University of California San Francisco. After establishing a 4-week baseline of frequency, type of seizures and existing antiepileptic drug (AED) regimes, patients received a purified 98% oil-based CBD extract, of known and constant composition at a dose of 5mg/kg/day in addition to their baseline AED regimen. The daily dose was gradually increased until intolerance occurred or a maximum dose of 25 mg/kg/day was achieved. After three months of therapy, 39% of patients had a greater than 50% reduction in seizures with a median reduction of 32%. Seizure freedom occurred in 3/9 Dravet patients and 1/14 patients with other forms of epilepsy. Adverse effects were mostly mild or moderate and included somnolence, fatigue, AED level increases, decreased appetite, weight gain, diarrhea, increased appetite and weight loss.

“These results are encouraging, especially since they involved a group of children and young adults with very treatment-resistant epilepsy. However, we await the planned double-blind study to truly assess the safety and efficacy of Epidiolex,” said Orrin Devinsky, M.D., director of the NYU Comprehensive Epilepsy Center and professor of neurology, neurosurgery and psychiatry at the NYU School of Medicine.

The second abstract related to Epidiolex (Poster #2.309) examined the drug interactions between existing AEDs and the CBD extract Epidiolex. In this study, 33 patients (with an average age of 10) were taking an average of three different AEDs including clobazam (54.5% of patients), valproate (36.4%) and levetiracetam (30.3%), felbamate (21.2%), lamotrigine (18.2%) and zonisamide (18.2%). Baseline AED concentrations were established and then taken again after the addition of CBD. Patients were given a purified 98% CBD extract, of known and constant composition starting at a dose of 5mg/kg/day and increasing by 5mg/kg/d every week until a maximal dose of 25mg/kg/d in addition to their baseline AEDs. The study found that in patients on multiple AEDs, the addition of CBD may be associated with changes in serum concentrations of some concomitant AEDs. A subset of patients experienced an increase in clobazam concentrations that was thought to be causing sedation and required a dose adjustment. This suggests CBD may have effects on the major metabolic pathways of clobazam.

“These results support experimental findings that CBD can affect metabolism of some common antiepileptic drugs though the effects may not be seen in all patients. More studies are needed to understand the potentially complex interactions between CBD and other drugs but in the meantime, frequent monitoring of drug levels is warranted in children taking CBD-containing products, including medicinal cannabis,” Daniel Friedman, M.D., epileptologist and a clinical neurophysiologist at the NYU Comprehensive Epilepsy Center.
The third abstract (Poster #2.405) explores the anticonvulsant effects and tolerability profile of plant derived CBD in both in vitro and in vivo models. Researchers at GW Pharmaceuticals explored five different models of seizure control as well as the use of CBD in combination with commonly used antiepileptic drugs on seizures. The study found that CBD significantly weakened status epilepticus-like conditions. In vivo, CBD exerted significant anticonvulsant effects in models of seizure. Moreover, CBD was well-tolerated and devoid of any negative drug-drug interactions when co-administrated with clinically used AEDs.

“These results demonstrate anticonvulsant effects of CBD in a broad range of in vitro and in vivo seizure models,” says Ben Whalley, professor of neuropharmacology at the School of Pharmacy, University of Reading, UK. “These data suggest that CBD may be a novel therapeutic candidate for a diverse range of human epilepsies, with a potentially favorable tolerability profile and support further clinical investigation.”

All three research studies will be provided in full at the American Epilepsy Society Annual Meeting in Seattle, December 5-9. Abstracts referenced above can be found on the American Epilepsy Society’s Annual Meeting Page.

**Editor’s Note:** Authors of these studies will be available at a press briefing on **December 8, 2014 at 1:30 PM (PT)/ 4:30 PM (ET)**, in the onsite press room, Room 304, Level 3 of the Washington State Convention Center. The call-in number for off-site journalists is 1-605-475-4000, passcode 521653#.

**About the American Epilepsy Society**
The American Epilepsy Society (AES) is a non-profit medical and scientific society. Our individual members are professionals engaged in both research and clinical care for people with epilepsy from private practice, academia and government. For more than 75 years, AES has been unlocking the potential of the clinical and research community by creating a dynamic global forum where professionals can share, learn and grow. AES champions the use of sound science and clinical care through the exchange of knowledge, by providing education and by furthering the advancement of the profession.

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