The Lancet Publishes Phase 3 Study of Epidiolex® (Cannabidiol) in Lennox-Gastaut Syndrome

LENNOX-GASTAUT SYNDROME (LGS)[1,2,3,4]

A rare, severe form of childhood-onset epilepsy that is difficult to treat

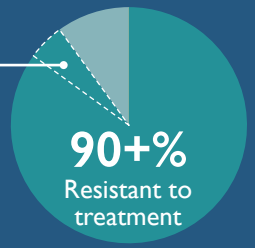
PREVALENCE

14K–18.5K children under 18 years old in U.S.

TYPICAL ONSET

A lifelong disease, LGS includes multiple seizure types, including drop seizures, which can lead to falls and injuries.

~3–7%
Die before age 11



LGS is debilitating and patients may experience intellectual disability, developmental delays and behavioral disturbances.

STUDY DESIGN

(NCT02224690, sponsored by GW Research, Ltd. Full study design available at www.clinicaltrials.gov.)

171 PATIENTS

15 AVERAGE AGE (RANGE 2–55)

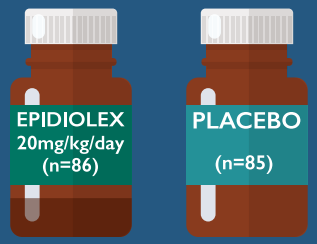
LGS PATIENTS IN THE STUDY

3 Were uncontrolled on a median of **3** other anti-epileptic drugs (AEDs)

6 Had tried and discontinued a median of **6** other AEDs

2 Had at least **2** drop seizures each week during the baseline period

2 STUDY ARMS
(added to existing treatment)



STUDY RESULTS

PRIMARY ENDPOINT

Patients taking Epidiolex experienced a significantly greater reduction (44%) in monthly drop seizure frequency compared to placebo (22%)

SECONDARY ENDPOINTS

Significantly more Epidiolex patients (44%) had a 50%+ reduction in drop seizures versus placebo (24%)

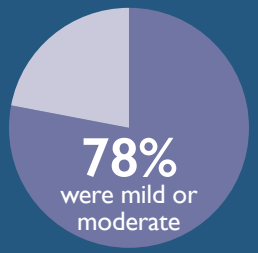
Total monthly seizures were significantly reduced with Epidiolex (41%) versus placebo (14%)

Significantly more caregivers reported their child's condition improved with Epidiolex (58%) versus placebo (34%)

SAFETY

Epidiolex was generally well tolerated in the trial. The pattern of adverse events (AEs) was consistent with previous data reported.

AEs WITH EPIDIOLEX



PATIENT DISCONTINUATIONS DUE TO AEs

- 86% of Epidiolex patients and 69% of placebo patients experienced AEs
- Most common AEs (>10%): diarrhea, somnolence, pyrexia, decreased appetite and vomiting

[1] Trevathan, E., Murphy, C.C. & Yeargin-Allsopp, M. Prevalence and descriptive epidemiology of Lennox-Gastaut syndrome among Atlanta children. *Epilepsia* 38, 1283-1288 (1997). [2] van Rijckevorsel, K. Treatment of Lennox-Gastaut syndrome: overview and recent findings. *Neuropsychiatric disease and treatment* 4, 1001-1019 (2008). [3] Cherian, K.A., Glauser, T.A., Morita, D.A. & Stannard, K.M. Lennox-Gastaut Syndrome. *in Medscape* (2016). [4] VanStraten, A.F. & Ng, Y.T. Update on the management of Lennox-Gastaut syndrome. *Pediatric neurology* 47, 153-161 (2012).

CONCLUSION: These results reinforce the utility of Epidiolex as a potential add-on treatment for patients with LGS.
Epidiolex (cannabidiol) is an investigational drug, under review by the FDA. Currently, it is not approved for any condition in any country.

For full information and disclosures, see press release available at http://ir.gwpharm.com/releases.cfm.