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

TWO TO EIGHT YEARS OF AGE

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

~3–7% Die before age 11

90+% Resistant to treatment

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

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)

4-WEEK Baseline | 14-WEEK Treatment Period

171 PATIENTS | AVERAGE AGE (RANGE 2–55)

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

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

78% were mild or moderate

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

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.

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