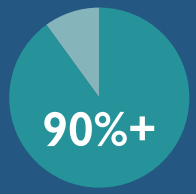
The New England Journal of Medicine Publishes Phase 3 Study of Epidiolex® (cannabidiol) in Dravet Syndrome

DRAVET SYNDROME[1,2,3,4,5]

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

90%+ of children are resistant to treatment



There are no medications approved for Dravet syndrome in the U.S.

Affects between 1 in 20,000 to 1 in 40,000 children (over 5,400 people under the age of 20 in the U.S.)

Typically develops in the first year of life

Lifelong disease with frequent and prolonged seizures, intellectual disability, developmental delays and behavioral disturbances

~15% die within 10 years of diagnosis

STUDY DESIGN

(NCT02091375, sponsored by GW Research, Ltd. Full study design available at www.clinicaltrials.gov.)

120 PATIENTS

10 AVERAGE AGE (RANGE 2–18)

PATIENTS IN THE STUDY

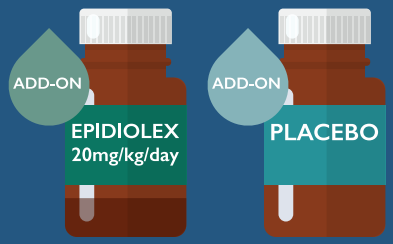
3 Were uncontrolled on a median of **3** other anti-epileptic drugs (AEDs)

4 Had tried and failed a median of **4** other AEDs

13 Had a median of **13** convulsive seizures per month (range 4 to 1,717)

2 STUDY ARMS

(added to current treatment)



STUDY RESULTS

PRIMARY ENDPOINT

Patients taking Epidiolex saw a significantly greater median reduction in convulsive seizures (39%) compared to placebo (13%)

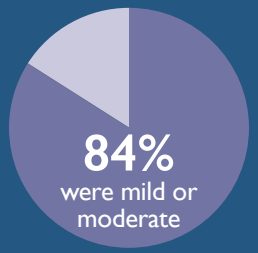
KEY SECONDARY ENDPOINTS

- More patients taking Epidiolex (43%) experienced a 50%+ reduction in convulsive seizures compared to placebo (27%)
- Significantly more caregivers reported that their child's overall condition improved with Epidiolex (62%) compared to placebo (34%)
- Total number of seizures was significantly reduced with Epidiolex compared to placebo

SAFETY

Epidiolex was generally well tolerated in this study. Adverse events (AEs) were consistent with previous data reported.

AEs WITH EPIDIOLEX



PATIENT DISCONTINUATIONS DUE TO AEs

- 93% of Epidiolex patients and 75% of placebo patients experienced AEs
- Most common AEs (>10%): somnolence, diarrhea, decreased appetite, fatigue, vomiting, pyrexia, lethargy, convulsion, upper respiratory tract infection

[1] http://www.epilepsy.com/learn/types-epilepsy-syndromes/dravet-syndrome [2] https://www.dravetfoundation.org/what-is-dravet-syndrome/ [3] Dravet C. The core Dravet syndrome phenotype. Epilepsia. 2011;52(Suppl. 2):3–9. [4] Cooper, M.S. et al. Mortality in Dravet syndrome. Epilepsy Research. 128 (2016) 43–47. [5] Forsgren, L. Incidence and prevalence. in: Wallace SJ, Farrell K (Eds.) Epilepsy in children. 2nd edn. Arnold, London; 2004: 21–25.

These results establish the potential of Epidiolex as an important new medicine for those with Dravet syndrome.
For full information and disclosures, see press release available at http://ir.gwpharm.com/releases.cfm

Epidiolex (cannabidiol) is an investigational product not approved for any condition in any country.