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

**DRAVET SYNDROME**
- 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.)

**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**
- 84% were mild or moderate
- 20mg/kg Epidiolex
- 8
- Placebo
- 1

**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

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.

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