Quality of Life and Sleep Assessments in Children with Developmental and Epileptic Encephalopathies Treated With ZYN002 (CBD) Transdermal Gel: BELIEVE (ZYN-CL02)

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BACKGROUND
- Developmental and epileptic encephalopathies (DEEs) are a severe group of neurodevelopmental disorders characterized by seizures, developmental delay, and medically refractory epilepsy.
- Cannabidiol (CBD) and tetrahydrocannabinol (THC) have shown promise in reducing seizures and improving quality of life in some patients with DEEs.

OBJECTIVE
- To evaluate the effects of ZYN002 transdermal CBD gel on QoL, sleep, and caregiver quality assessment in child and adolescent patients with DEEs.

METHODOLOGY
- STUDY DESIGN AND METHODS
  - ZYN002-CL02 (ZYN002) was an open-label, multicenter, multiple-dose, 2-phase study in children aged 1-18 years with >1 seizure in the previous 4 weeks and requiring treatment with ≥2 ASMs per day (Phase 1).
  - ZYN002 was administered in total daily doses of 250-1000 mg over an initial 26-week treatment period (Period A) followed by a up to 46-week extension (Period B).

RESULTS
- **BASELINE CHARACTERISTICS**
  - 74 eligible patients (48 males, 26 females; mean age 12.5 years) were enrolled and treated with ZYN002.
  - Patient characteristics: median (range) age 11.1 (3.5-18) years, weight 35.0 (21.0-85.0) kg, with 52% (n = 38) ≥18 years.

- **SLEEP ASSESSMENT**
  - Sleep assessment was conducted by caregivers using the Sleep Disturbance Scale for Children (SDSC) (Table 2).
  - **SLEEP SCALES**
    - Percentage of patients with a threshold =1.0 at Baseline and Week 26 shown in Figure 3.
    - Observed improvements in sleep scales were maintained through to Week 26.

- **QUALITATIVE CAREGIVER FEEDBACK**
  - **Good Day/Bad Day**
    - 58% (n=43) caregivers reported 100% days as good or very good.
    - 60% of caregivers provided ≥1 statement about improvement.
    - Most treatment-emergent adverse events (TEAEs) were mild or moderate.

- **GOOD DAY/BAD DAY ASSESSMENT**
  - Statistically significant improvements from baseline to Week 26 shown in Table 4.
  - There were no statistically significant changes in baseline sleep scales were observed.

- **GOOD OUTCOMES**
  - Statistically significant improvements from baseline to Week 26 shown in Figure 5.
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