Patients (20.8%) reported a serious AE (SAE); most were infection-related. There were no clinically significant changes in vital signs, ECGs, or laboratory tests.

**BACKGROUND**

- Developmental and epileptic encephalopathies (DEEs) are a group of neurodevelopmental disorders characterized by seizures and abnormal electroencephalogram activity that negatively impact development.
- DEEs include, but are not limited to, West syndrome, Lennox-Gastaut syndrome (LGS), and Dravet syndrome.
- DEEs have an incidence of 1 in 20,000 live births (0.5%–1.5%) and are associated with increased risk for mortality.

**OBJECTIVE**

- To evaluate the safety, tolerability, and efficacy of ZYN002 in children and adolescent patients with DEEs.

**METHODS**

**STUDY DESIGN AND TREATMENT**

- ZYN002-CL-025 (BELIEVE) was an open-label, two-center, multiple-dose, single-blind, therapeutic trial.
- ZYN002 is a pharmaceutically manufactured transdermal CBD gel currently in development for the reduction of seizures in patients with DEEs.

**RESULTS**

- Baseline demographics and disease characteristics of patients included in the study are presented in Table 1.

**SAFETY**

- Most patients (n = 40) experienced one or more adverse events (AEs) during the study.
- The percentage of patients meeting ≥35% and ≥50% reduction in FIAS and TCS with CBD Q12H was 45.5% and 55.2%, respectively, at month 6 for FIAS, GTCS, and BTCS.

**CONCLUSIONS**

- ZYN002 is well tolerated during 26 weeks of treatment in a medically fragile patient population of children and adolescents with DEEs.
- The benefit-risk profile of ZYN002 in this trial supports further study in patients with DEEs and FIAS and TCS.

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**Table 1. Baseline Demographics and Disease Characteristics, Safety Analysis Set**

<table>
<thead>
<tr>
<th>Demographic or Disease Characteristic</th>
<th>Safety Analysis Set (N = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>Mean (range)</td>
</tr>
<tr>
<td>13.5 (11-16)</td>
<td></td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td>Male</td>
</tr>
<tr>
<td>20 (50)</td>
<td>20 (50)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>23.9 (4.2)</td>
<td></td>
</tr>
<tr>
<td>Diagnosis, n (%)</td>
<td>Dravet Syndrome</td>
</tr>
<tr>
<td>8 (20)</td>
<td>10 (25)</td>
</tr>
<tr>
<td>Seizure type, n (%)</td>
<td>Focal impaired awareness</td>
</tr>
<tr>
<td>26 (65)</td>
<td>12 (30)</td>
</tr>
</tbody>
</table>

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**Figure 1. BELIEVE Study Design**

**Figure 2. Median Percentage Reduction From Baseline in 28-Day Frequency of FIAS and TCS by Time Point During Period A, mITT Population With FIAS and/or TCS at Baseline (N = 33)**

**Figure 3. Percent of Patients With 35% and 50% Reduction From Baseline in 28-Day Frequency of FIAS and TCS at Month 6, mITT Population With FIAS and/or TCS at Baseline (N = 40)**

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**REFERENCES**