**Introduction**

Dravet syndrome (DS) is a severe, drug-resistant epileptic encephalopathy that has its onset during the first year of life. Current treatment options, commonly sodium-channel blockers and corticosteroids, fully control tonic-clonic seizures in <25% of patients, and nearly 50% of treated patients continue to experience >4 tonic-clonic seizures per month. Of Rety and colleagues, who recently reported that uncontrolled seizures in early-onset epilepsy (ages 2 years or younger) were significantly associated with poor cognitive outcomes, underscoring the need for earlier treatment options that can provide clinically meaningful, sustained reductions in seizure frequency.

Two recent Phase 3 clinical trials have reported dramatic decreases in the frequency of major motor seizures in children and adolescents with DS aged 2 to 18 years who were treated with fenfluramine added to their current antiepilepsy drug regimen.

Here we present an analysis evaluating the effectiveness of fenfluramine by age group in a long-term open-label extension study (OLE).

**Methods**

Patients with DS aged 2 to 18 years who completed either of the two Phase 3 clinical trials entered an OLE of fenfluramine (Table 1).

- All patients in the OLE group started treatment with a fenfluramine dose of 0.2 mg/kg/day, and the dose was titrated to optimal effect (maximum dose was 0.7 mg/kg/day, total dose of 26 mg/day), or in patients who were also receiving stiripentol, to fenfluramine 0.4 mg/kg/day (maximum total dose of 17 mg/day).

Fenfluramine was administered as an oral solution of fenfluramine HCl containing 2.2 mg/mL fenfluramine. Baseline convulsive seizure frequency was determined during the baseline period in the core clinical trial. Efficacy and tolerability were assessed at months 1, 2, and 3, and thereafter at 3-month intervals.

**Results**

138 patients who completed one of the two Phase 3 clinical trials enrolled in the OLE.

Demographics and baseline characteristics are shown in Table 1.

109 patients (81%) discontinued the OLE due to:
- Lack of efficacy (n=71)
- Withdrawal by patient (n=2)
- Physician decision (n=2)
- Adverse event (n=1)
- Sudden unexpected death in epilepsy (SUDEP) (n=1)
- Other (n=1)

42/158 patients (26.4%) were <6 years at entry into the core Phase 3 clinical trial.

Fenfluramine provided sustained, clinically meaningful reduction in convulsive seizure frequency in young patients (<6 years old) that was similar to that observed in older patients (≥6 years old) and overall patient population (Figure 1).

**Conclusion**

Fenfluramine provided sustained, clinically meaningful reduction in convulsive seizure frequency in young patients (<6 years old) that was similar to that observed in older patients and overall patient population. Treatment with fenfluramine provided sustained, clinically meaningful reduction in convulsive seizure frequency in young patients that was similar to that observed in older patients and overall patient population.

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**Disclosures**

No conflicts of interest were declared.

**References**