Fintepla® (Fenfluramine HCl Oral Solution) Provides Long-Term Clinically Meaningful Reduction in Seizure Frequency: Results of an Open-Label Extension Study

Introduction

Dravet syndrome (DS) is a rare, severe, treatment-resistant epileptic encephalopathy. In two recently completed phase 3, double-blind, placebo-controlled clinical studies, fenfluramine (FFA) demonstrated clinically meaningful (≥50%) reduction in convulsive seizure frequency in children 6-18 years with DS. A majority of patients responded to FFA over the entire OLE interim analysis period (median 256 days) of the OLE study. FFA 0.5 mg/kg/day demonstrated superior efficacy compared with placebo for the reduction in convulsive seizure frequency in children 6-18 years with DS in the core clinical study. The mean age was 9.1±4.7 years (range 1.1-19.5 years). 45 patients were randomized into the core clinical study and 72 patients were randomized to the open-label extension (OLE) study. A clinically meaningful (≥50%) reduction in convulsive seizure frequency was observed in 64.4% of patients in the core clinical study, including in most patients originally enrolled with adverse events.* Safety

Adverse events occurring in ≥5% of patients are shown in Table 3. The most common adverse events (≥5%) in the core clinical study were decreased appetite (64.8%), weight loss (44.8%), pyrexia (25.4%), nasopharyngitis (20.3%), urinary tract infection (12.6%), and abdominal pain (10.8%). The majority of adverse events were mild or moderate in severity. Adverse events were observed in 64.4% of patients in the core clinical study, including in most patients originally enrolled with adverse events.*

Conclusions

Fintepla® (fenfluramine HCl oral solution) demonstrated clinically meaningful (≥50%) reduction in convulsive seizure frequency in children 6-18 years with DS treated with FFA 0.5 mg/kg/day in the core clinical study and in the OLE study (median 256 days) compared with placebo. Fintepla® (fenfluramine HCl oral solution) is currently only indicated for the treatment of children 6-18 years old with DS. Additional studies are needed to further support the benefits of fenfluramine in children with DS. Fintepla® is not recommended for the treatment of SUDEP (sudden unexpected death in epilepsy). *Privacy laws in some regions/countries preclude disclosure of certain personal information.