Dravet syndrome (DS) is a rare, severe, treatment-resistant, epilepsy with
FFA was commonly used in combination with other antiepileptic drugs.
Approximately 161 patient-years of echocardiographic data were obtained from 116 patients who were enrolled in the open-label extension (OLE) study (NCT02823145) and had completed the phase 3 studies.

All ECHOs were performed with standardized views and machine settings.

No VHD or PAH has been observed in this OLE study, during the 2 years of treatment with FFA.

The threshold for potential PAH was set as pulmonary arterial systolic pressure >35 mmHg. A total of 703 ECHOs have been performed and analyzed with standardized views and machine settings. The decrease in N is due to the staggered entry into the study and not due to patient withdrawals.

In 2 recently completed phase 3, double-blind, parallel-group, placebo-controlled clinical studies, low-dose fenfluramine (FFA) demonstrated profound reduction in frequency of convulsive seizures in patients with DS and young adults with CDH.

In the first study (Study 1), FFA 0.8 mg/kg/day (maximum 30 mg/day) was administered for 52 weeks, and 0.4 mg/kg/day (maximum 15 mg/day) was administered for an additional 26 weeks, with a total of 18 million prescriptions written in the US in 1996, and was withdrawn following reports of valvular heart disease.

FFA was commonly used in combination with phenobarbital.

Doses up to 120 mg/day were reported.

The majority of reported cases had no pretreatment cardiac valve function within the normal range (absent=0, trace=1, mild=2, moderate=3, severe=4).

In the second study (Study 2), FFA 0.2 mg/kg/day (maximum 20 mg/day) was administered for 26 weeks, and 0.06 mg/kg/day (maximum 2 mg/day) was administered for an additional 26 weeks, with a total of 18 million prescriptions written in the US in 1996, and was withdrawn following reports of valvular heart disease.

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