Improved Everyday Executive Function With Fintepla® (Fenfluramine HCI Oral Solution): Results From a Phase 3 Study in Young Adults With Dravet Syndrome

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ABSTRACT: Fintepla® (fenfluramine HCI oral solution) is a prodrug approved for the treatment of Dravet syndrome (DS) in patients ages 12 years and older who are able to tolerate the oral route of administration. Fenfluramine is rapidly metabolized to fenfluramine acid, which is the active metabolite that provides efficacy in DS. This post hoc analysis evaluated the impact of fenfluramine acid on two key functional domains, emotion regulation and executive function, assessed using the Emotion Regulation Index (ERI) and the Behavior Regulation Index (BRIEF) in patients with DS. A total of 77 patients had BRIEF 2 scores that met the inclusion criteria. A significant, clinically meaningful difference among the 3 treatment groups was shown on the inhibit, self-monitor, shift, and emotional control BRIEF 2 scales, as well as the Behavior Regulation Index (BRIEF) and Emotion Regulation Index (ERI). A significant increase in the percentage of patients meeting the Reliable Change Index (RCI) was shown in the fenfluramine acid groups compared with placebo. A significant increase in the percentage of patients meeting the Reliable Change Index (RCI) was shown in the fenfluramine acid groups compared with placebo. Significant improvements were shown in all five of the ERI subscales and in ERI composite (GEC) with fenfluramine acid compared with placebo. A significant increase in the percentage of patients meeting the Reliable Change Index (RCI) was shown in the fenfluramine acid groups compared with placebo. Significant improvements were shown in all five of the ERI subscales and in ERI composite (GEC) with fenfluramine acid compared with placebo. Significant improvements were shown in all five of the ERI subscales and in ERI composite (GEC) with fenfluramine acid compared with placebo. Significant improvements were shown in all five of the ERI subscales and in ERI composite (GEC) with fenfluramine acid compared with placebo. Significant improvements were shown in all five of the ERI subscales and in ERI composite (GEC) with fenfluramine acid compared with placebo. Significant improvements were shown in all five of the ERI subscales and in ERI composite (GEC) with fenfluramine acid compared with placebo.