Efficacy of FT218 on Polysonmographic Measures of Sleep Continuity in Patients with Narcolepsy: Results From the REST-ON Trial

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Background

The REST-ON trial (NCT02702744) was a Phase 3 multicenter, randomized, double-blind, placebo-controlled study of FT218 (once-nightly sodium oxybate) to evaluate the efficacy and safety of FT218 for the treatment of patients with narcolepsy with sleep attacks and cataplexy. FT218 is currently approved for the treatment of narcolepsy with cataplexy.

Methods

Study Design and Procedures

Determined detailed methods including participant inclusion/exclusion criteria, concomitant medications, and study design, from the phase 3 REST-ON clinical trial are presented in Poster #489. In the REST-ON trial, participants received either 6 g ON-SXB (n=107) or placebo (n=105) for 26 weeks. The primary endpoint was change in number of shifts (DNS, defined in this clinical trial as the number of shifts from stage N2, N3, and REM sleep to wake and from stages N2, N3, and REM sleep to stage N1). The secondary endpoints included the following PSG measures: time spent in N1 and N3 sleep, highlighting the decrease in time spent in lighter sleep vs placebo including time spent in N1 and N3 sleep, highlighting the decrease in time spent in lighter sleep vs placebo (Figures 3 and 4). In the safety population, 83 (77.6%) and 49 (46.7%) participants in the ON-SXB and placebo groups, respectively, experienced a treatment-emergent AE; 3 (2.8%) and 4 (3.8%) participants treated with ON-SXB at each dose (and more frequently than placebo) across doses of 4.5, 6, 7.5, and 9 g were enureric (2%–7%), headache (0%–7%), dizziness (4%–6%), nausea (3%–4%), somnolence (0%–3%) and decreased appetite (3%–4%), decreased weight (0%–3%), and anorexia (1%–3%), and somnambulism (0%–2%). Safety Outcomes

Conclusions

At all doses evaluated 6, 7.5, and 9 g, ON-SXB demonstrated significant consolidation of nocturnal sleep, significant improvement in time spent in deep sleep, and significant decrease in time spent in lighter sleep vs placebo. Placebo alone did not impact key measures of sleep, including time spent in N1 and N3 sleep, highlighting the efficacy of ON-SXB on these objective endpoints. ON-SXB was generally well tolerated; the most common adverse reactions were recognized adverse reactions of SXB and ON-SXB, if approved by the FDA, will offer a new once-nightly treatment option for adults with narcolepsy experiencing EDS or cataplexy, as well as improvements on DINs, as demonstrated by PSG measures.