Brain Neuromodulation Digital Therapeutics For Migraine

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INTRODUCTION

Relivion® is the first non-invasive multi-channel brain neuromodulation technology for treating neurological and neuropsychiatric disorders. It offers precise, personalized care by delivering stimulation to six branches of the occipital and trigeminal nerves via three adaptive output channels (Fig.1). Electro-physiologically, it creates a cumulative effect by releasing neurotransmitters in the brainstem and modulate brain networks associated in control of pain and mood.

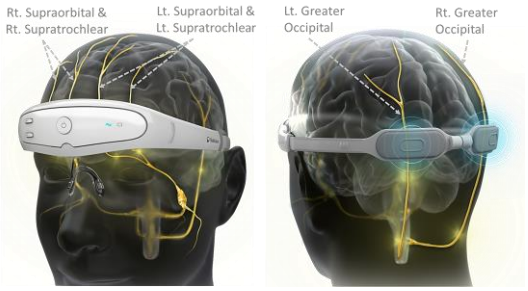

Fig. 1: *The combined occipital & trigeminal neurostimulation device*

During treatment, the Relivion e-Relief™ mobile App gather treatment data from the device and upload it to a secure cloud database for analysis and treatment optimization.

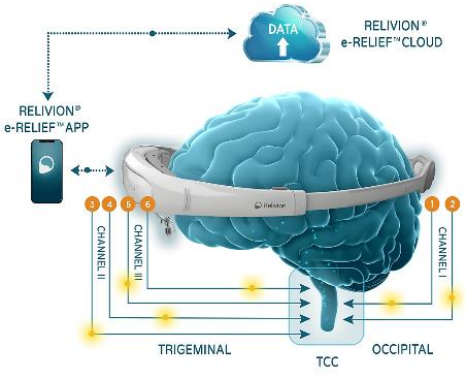

Fig. 2: *The Digital Therapeutics Ecosystem*

METHODS

A randomized, double-blind, parallel-group, sham-controlled clinical study, designed to evaluate the safety and efficacy of the Relivion device in the acute treatment of episodic and chronic migraine.

RESULTS

55 subjects were randomized and self-treated one migraine episode. Following one-hour treatment, pain decreased significantly more in the treatment group compared to the sham group at all time points (group difference at 1-hour 41% p=0.0002, at 2-hours 33% p=0.03, at 24-hours 36% p=0.02). Responders rate was also significantly higher in the treatment group than in the sham group at 1-hour (67% ver. 20%, p=0.001), 2-hours (67% ver. 32%, p=0.02) and 24-hours (78% ver. 48%, p-=0.04). Pain free at 2-hours for subjects with a baseline pain level of sever-moderate was significantly higher in the treatment group than in the sham group (43% versus 11%, p= 0.02). Headache relief rate (subjects which improved from severe or moderate pain at baseline to mild or no pain) was significantly higher in the treatment group compared to the sham group at 1-hour (66.7% ver. 26.3%, p=0.01) and 2-hours (76.2% ver. 31.6%, p= 0.01) (Fig.3) test points.

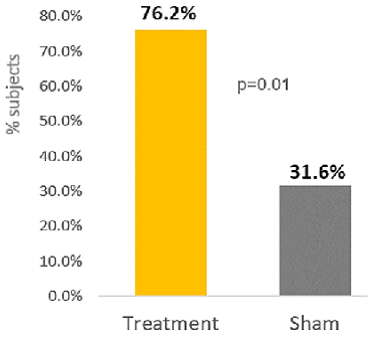

Fig. 3: *Headache Relief after 2 hours*

DISCUSSION & CONCLUSIONS

The results demonstrate that acute treatment of migraine by the Relivion device was safe and highly effective. We hypothesize that the synergistic neuromodulatory effect elicited by concurrent activation of the occipital and trigeminal neural pathways contributes to the superior therapeutic results shown in these studies.