Objective

To assess the PD effects of single doses of BHV-7000 on EEG spectral power in healthy adults.

Methods

A phase 1 open-label clinical trial was conducted in healthy adult males and females aged 18–55 years.

Subjects received single oral doses of BHV-7000 10, 25, and 50 mg (standard formulation) on days 1, 5, and 9 in a randomized sequence.

Baseline was assessed on day -1, when no dose was given.

All subjects underwent sequential EEG recordings with the international 10-20 electrode setup at days -1, 1, 5, and 9.

EEG measurements were collected by Stratus (Irving, TX), using a 5-minute period of resting state with eyes open and 5 minutes of resting state with eyes closed at baseline, predose, 1, 2, 3, 4, and 6 h post drug intake. Data reported in this analysis are with eyes open.

EEG concentrations of BHV-7000 were quantified at corresponding time points.

RESULTS

BHV-7000 Has Greatest Impact on Alpha

Dependent Impact on Delta and Theta

Figure 1. Spectral Power in Resting-State EEGs: BHV-7000 Has Greatest Impact on Alpha; Minimal Impact on Delta and Theta

Spectrum at Broadband Max Response

BHV-7000 50 mg vs Baseline

Box 1. Quantitative Spectral Analysis

Quantitative EEG (qEEG) is an advanced technique to quantify and analyze electrical activity of the brain in a standardized and objective manner, helping clinicians and researchers gain insights into brain function.

Spectral analysis is a fundamental method used in qEEG to quantify the power, spatial distribution, and peaks of rhythmic brain activity. Changes in spectral power have been linked to epileptogenesis and seizure prediction and detection in epilepsy and cognitive changes, awareness, and treatment efficacy in neurological disorders.

In this study, the EEGs were preprocessed to remove muscle and eye artifacts and environmental noise. Current source density analysis was applied to estimate the radial current flow at the scalp, leading to more spatially distinct and preference-free topographies.

FFT was applied to extract the spectrum in epochs of 3 seconds. From these, the peak power, frequency, and peak of the corresponding topography in the canonical frequency bands (delta [1-3.5 Hz], theta [3.5-7.5 Hz], alpha [7.5-13 Hz], beta [13-30 Hz], and gamma [30-100 Hz]) were derived.

Changes in spectral power of various frequencies at baseline (day -1: blue) and BHV-7000 50 mg dose (red). Shading represents the standard error of measurement.

Figure 2. BHV-7000 Shows Dose-Dependent Increases in EEG Spectral Power

Relative Power Change Postdose

BHV-7000 – Baseline

10 mg

25 mg

50 mg

Alpha

Theta

Gamma

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