Clinical Safety and Efficacy of an At-Home, Dual Wavelength Red Light Hair Growth System in Subjects with Androgenetic Alopecia

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Objective

Dual Wavelength Device (REVIAN® RED)

Methods

REVIAN Red® is an FDA-cleared low-level light therapy device (K173729) used to promote hair growth. To evaluate the safety and efficacy of the dual wavelength LED light device in men and women with androgenetic alopecia we conducted a 26 week, multicenter, prospective, randomized, controlled, double-blind, study.

Eighty-one subjects were randomized to either a dual wavelength 620 nm and 660 nm light therapy device paired with a Bluetooth-connected mobile app (REVIAN RED System) or to a sham comparator device with a similar user experience through the mobile app to track daily treatment compliance between both groups. Device usage was fixed at once daily, 10-minute treatment durations for a period of 26-weeks. The trial population consisted of adult men and women between 18 and 65 years of age with a diagnosis of androgenetic alopecia, consistent with males who have Norwood Hamilton Classification IIa to V patterns of hair loss and females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal, both with Fitzpatrick Skin Types I - IV.

Results

The primary endpoint was the mean change in target area hair count between active and sham-treated subjects at week 16. The efficacy evaluable population was defined as subjects who completed at least 16 weeks of treatment, had no major protocol violations, and who were at least 80% compliant with the 10 minutes per day treatment regimen for the duration of the trial. After 16 weeks, subjects that were treated with the dual wavelength red light device and were at least 80% compliant (n=18) had a mean change of 26.3 more hairs per cm² compared to those participants who wore a sham cap, identical in appearance but received no light therapy (n=18).

Conclusion

REVIAN RED is a safe and effective alternative to chemical-based topical and prescription therapies for patients with androgenetic alopecia with results seen as early as 16 weeks.