LIGHTSITE III met the primary efficacy endpoint with a statistically significant improvement in BCVA in the PBM versus the Sham group at Month 13 (p = 0.02), with maintained significance at Month 24 (p = 0.0015)

- More patients lost BCVA in the Sham group compared to the PBM group at Month 13 and 24
- A numerical increase in drusen volume was observed in the Sham group versus no increase in the PBM group at Month 13 and 24 (~4-fold increase over PBM)
- Occurrence of new GA was observed in 24.0% of Sham versus 6.8% of PBM-treated eyes. Occurrence of new GA was significantly higher in the Sham group versus the PBM group (p = 0.007, Fisher exact test, odds ratio 4.2 at Month 24)
- A favorable safety profile was observed with no signs of phototoxicity
- LIGHTSITE III showed significant improvements in clinical and anatomical outcomes suggesting a disease modifying benefit

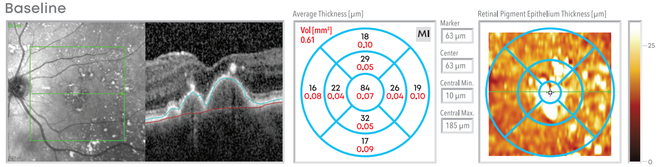
Individual Patient Results

This patient presented with reduction of drusen volume without progressive outer retinal degeneration. At Month 13, a significant reduction in drusen volume and no visible loss of photoreceptor/retinal pigment epithelium cells was observed.

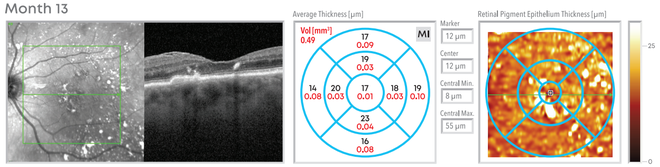
Age: 77 years
Sex: Female

Baseline BCVA: 75 letters
Month 13 BCVA: 79 letters
Month 24 BCVA: 80 letters

Baseline



Month 13



*Individual patient results may vary

INDICATIONS FOR USE

The indicated use is for treatment of ocular damage and disease using photobiomodulation, including inhibition of inflammatory mediators, edema or drusen deposition, improvement of wound healing following ocular trauma or surgery, and increase in visual acuity and contrast sensitivity in patients with degenerative diseases such as dry age-related macular degeneration.

VALEDA

+44-2076601516
www.lumithera.com
Not for sale in the US

LumiThera

CE 2797 | UKCA 0086

LumiThera, Inc.
19578 10th Ave NE STE 200, Poulsbo, Washington 98370 USA

MKT-0085 REV B

First Approved Treatment for Dry Age-Related Macular Degeneration Using Photobiomodulation

LIGHTSITE III Month 24 Trial Results

VALEDA
Light Delivery System

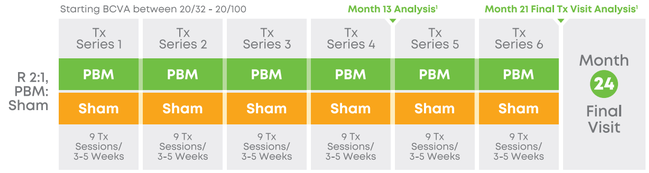
- Improves and Sustains Visual Acuity in Early to Intermediate Dry AMD Patients
- Reduces Development of Geographic Atrophy
- Slows Progression of Disease

LIGHTSITE III Month 24 Analysis

Double-masked, randomized, sham-controlled, parallel group, multi-center trial to assess the safety and efficacy of photobiomodulation (PBM) in subjects with dry age-related macular degeneration (AMD)

LIGHTSITE III Trial Design

- PBM treatment (Tx): 590, 660, and 850 nm wavelengths
- Sham Tx: 50x/100x reduction of 590/660 nm; No 850 nm wavelengths



[1]Primary endpoint: 13-month comparison between PBM and Sham groups. This trial summary includes data from the Month 13 (primary endpoint), Month 21 (final treatment visit), and Month 24 (final trial visit – 3 months following last treatment) timepoints.

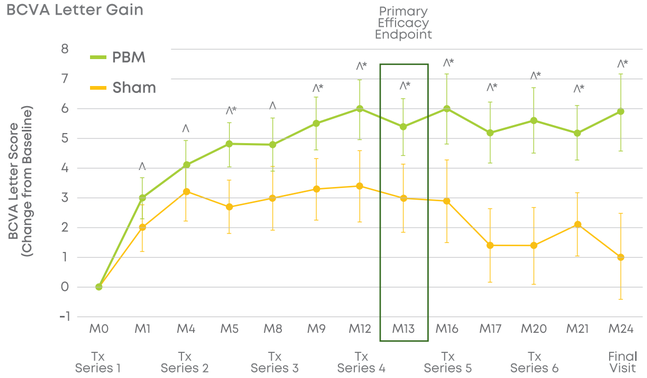
Patients - Baseline Characteristics

Patients - 100 (98 subjects mITT analysis)
Eyes - 148 (145 eyes mITT analysis)
Randomisation - 2:1 PBM to Sham
Race - 99% Caucasian, 1% Black/African American
Gender - 32 M (32%), 68 F (68%)
Mean Age - 75 years
Mean Time from Diagnosis - 4.9 years
AREDS supplements - 86 (86%) yes, 14 (14%) no
BCVA Baseline (BL) ≥ 70 letters (20/40) - 103 eyes (70%)
BCVA Letter Score - PBM: 70.7 letters (SE 0.55); Sham: 70.1 letters (SE 0.58)

Valeda Improved Vision

- PBM demonstrated a statistically significant difference in BCVA between PBM and Sham Groups at Month 13 (p = 0.02) and Month 24 (p = 0.0015)
- PBM provided improved and sustained BCVA with a mean 5.4 letter gain from BL at Month 13 (p < 0.0001) and mean 5.9 letter gain from BL at Month 24 (p < 0.0001)

BCVA Letter Gain

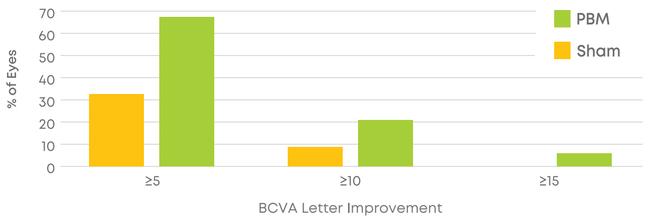


80 subjects/113 eyes completed through Month 24

^ p < 0.0001, within group comparison (PBM). * p < 0.05, between group comparison. Post-treatment means include data from the Last observation carried forward. Within group comparisons (Sham) showed significant differences at all timepoints (p < 0.0001).

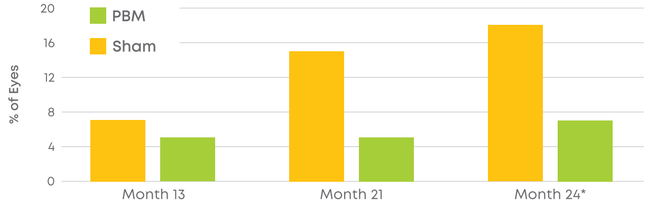
BCVA Letter Gain Distribution at Month 24*

67.2% ≥ 5 letter gain | **20.9%** ≥ 10 letter gain | **6.0%** ≥ 15 letter gain



*Number of actual patients used for BCVA letter gain at Month 24

BCVA >5 Letter Loss Over 24 Months

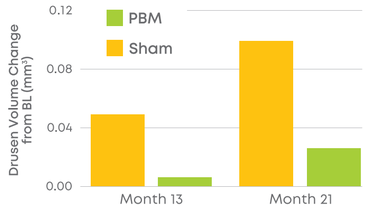


*Number of actual patients used for % of >5 BCVA letter loss at Month 24

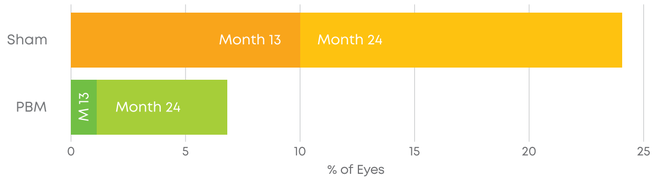
Potential Disease-Modifying Effects Observed Following PBM Treatment

A greater numerical increase in drusen volume was observed in Sham versus PBM-treated eyes at Month 13 and 21

- At Month 13, > 3x increase in drusen volume in Sham versus PBM-treated eyes
- At Month 21, ~ 4x increase in drusen volume in Sham versus PBM-treated eyes



Occurrence of new geographic atrophy (GA) was significantly higher in the Sham group versus the PBM group at Month 13 and 24*



*Month 13 (p = 0.024, Fisher exact test, odds ratio 9.4) and at Month 24 (p = 0.007, Fisher exact test, odds ration 4.2)