VALEDA®

Light Delivery System

The First and Only Treatment for Dry AMD

It's Time for Patients to See Their Future

LIGHTSITE III

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

Baseline Characteristics

Subjects: 100 (98 subjects mITT analysis)
Eyes: 148 (145 eyes mITT analysis)
Randomization: 2:1 PBM to Sham
Race: 99% Caucasian; 1% Black/African American
Gender: 32 Males (32%); 68 Females (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 (SD 5.2); Sham: 70.1 letters (SD 4.3)

LIGHTSITE III Trial Design

- **PBM: 590, 660, and 850 nm wavelengths**
- **Sham: 10x reduction of 590 nm, 100x reduction of 660 nm, and no 850 nm wavelengths**

Starting BCVA between 20/32 - 20/100

Month 13 Analysis[1] **Month 21 Final Tx Visit Analysis[1]**

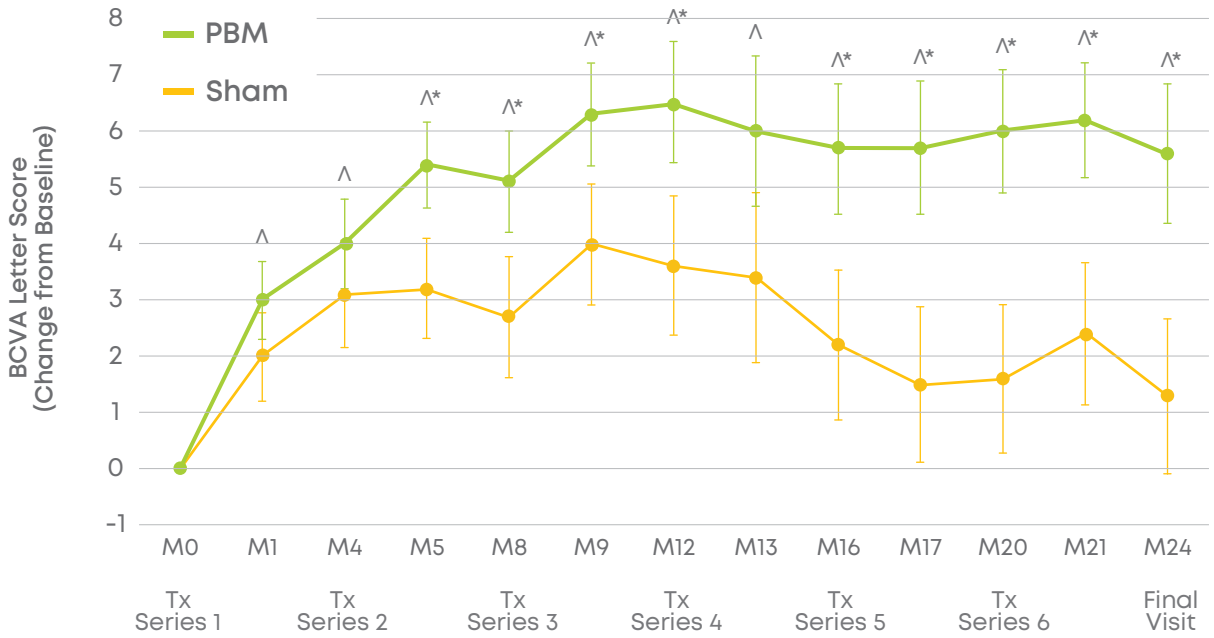
Tx Series 1	Tx Series 2	Tx Series 3	Tx Series 4	Tx Series 5	Tx Series 6	Month 24 Final Visit
PBM	PBM	PBM	PBM	PBM	PBM	
Sham	Sham	Sham	Sham	Sham	Sham	
9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	

[1]Co-primary endpoints: 13- and 21-Month comparison between PBM and Sham groups. This trial summary includes data from Month 13, Month 21, and Month 24 (3 months following last treatment).

Valeda Improves and Maintains Vision

- PBM demonstrates a benefit in BCVA versus Sham over the course of the study. The primary BCVA endpoint at Month 21 had a p value = 0.0036
- PBM improves BCVA with a mean 6.0 letter gain from BL at Month 13 ($p < 0.0001$) and maintains a mean 6.2 letter gain from BL at Month 21 ($p < 0.0001$)

BCVA Letter Gain

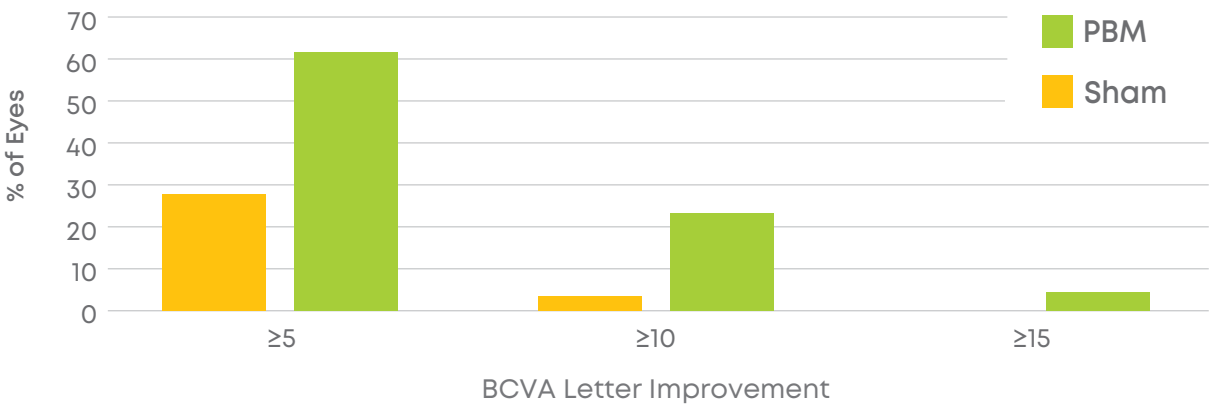


80 subjects/113 eyes completed through Month 24

The least squares (LS) mean data using multiple imputation and standard error (SE) is presented. * $p < 0.05$ between group comparison; ^ $p < 0.0001$ within group comparison (PBM).

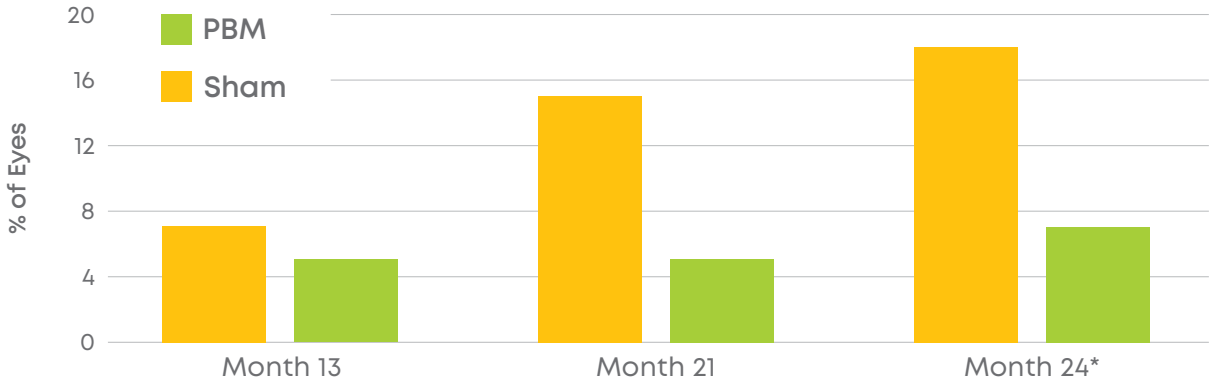
BCVA Letter Gain Distribution at Month 21*

61.5%	23.1%	4.4%
≥5 letter gain	≥10 letter gain	≥15 letter gain



*Data presented with multiple imputation at Month 21.

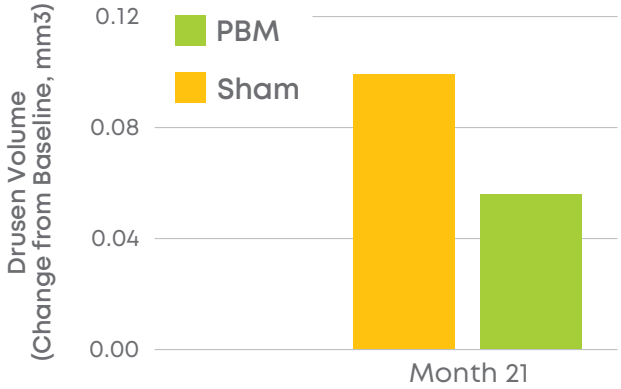
BCVA >5 Letter Loss Over 24 Months*



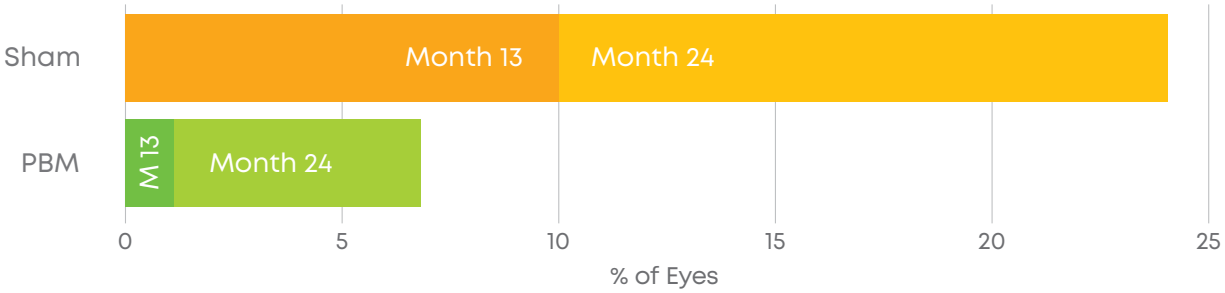
*Number of actual eyes used for percentage of >5 BCVA letter loss at Month 24

A Greater Numerical Increase in Macular Drusen Volume Observed in Sham Group Versus PBM Group

*Data presented with multiple imputation at Month 21.



Incident Geographic Atrophy (GA) was Higher in the Sham Group Versus the PBM Group at Months 13 and 24†



†Incident GA was not a pre-specified endpoint. Month 13 (p = 0.024, Fisher exact test, odds ratio 9.4) and Month 24 (p = 0.007, Fisher exact test, odds ratio 4.2)

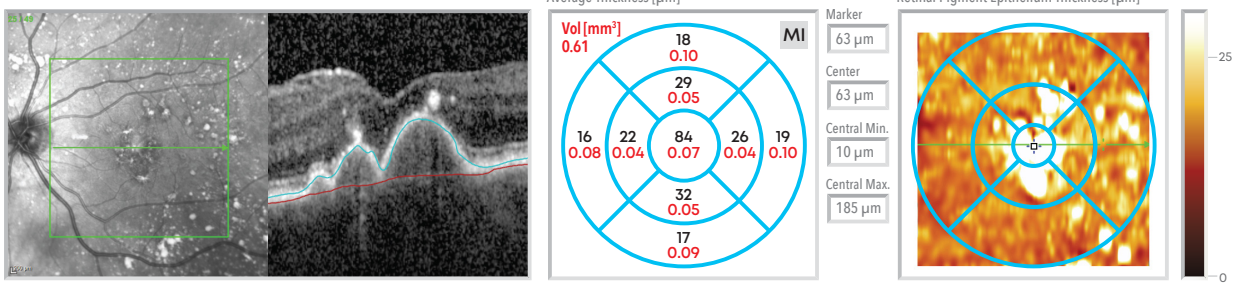
Individual Patient Results

This patient presented with reduction of macular 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 were observed.

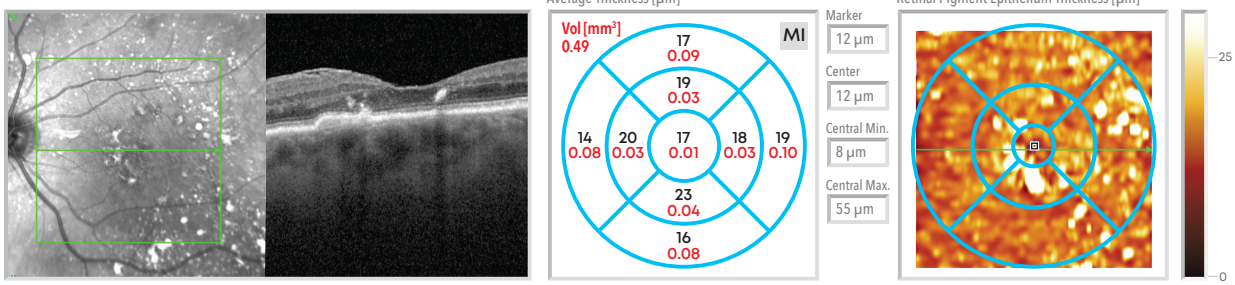
Age: 77 years
Sex: Female

Baseline BCVA*: 75 letters
Month 13 BCVA: 79 letters
Month 21 BCVA: 84 letters
Month 24 BCVA: 82 letters

Baseline



Month 13



Individual patient results may vary

*OCT imaging and BCVA measurement taken at screening visit.

Valeda Demonstrates Improvements in Clinical and Anatomical Outcomes Supporting a Disease-Modifying Benefit

- PBM demonstrates a benefit in BCVA versus Sham over the course of the study. The primary BCVA endpoint at Month 21 had a p value = 0.0036
- More subjects lost BCVA in the Sham group compared to the PBM group at Months 13, 21, and 24
- A greater numerical increase in macular drusen volume was observed in the Sham group versus the PBM group
- Incident GA was observed in 24.0% of Sham versus 6.8% of PBM-treated eyes at Month 24†
- A favorable safety profile was observed with no signs of phototoxicity

Indications for Use

The Valeda Light Delivery System is intended to provide improved visual acuity in patients with best-corrected visual acuity of 20/32 through 20/70 and who have dry age-related macular degeneration (AMD) characterized by:

- The presence of at least 3 medium drusen {> 63 µm and ≤ 125 µm in diameter), or large drusen {> 125 µm in diameter), or non-central geographic atrophy, AND
- The absence of neovascular maculopathy or center-involving geographic atrophy

After about two years, the Valeda Light Delivery System treatment provides improved mean visual acuity of approximately one line of visual acuity (ETDRS) compared to those not receiving the treatment.

Contraindications For Use

As a precaution, patients have not been tested and should not be treated with Valeda if they have any known photosensitivity to yellow light, red light or near-infrared radiation (NIR), or if they have a history of light activated central nervous system disorders (e.g., epilepsy, migraine). In addition, patients should not receive treatment within 30 days of using photosensitizing agents (e.g., topicals, injectables) that are affected by 590, 660, and/or 850 nm light before consulting with their physician.

Refer to the Valeda Light Delivery System User Manual for full Important Safety Information.

Rx Only

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+1-844-342-3333
www.valeda.com

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