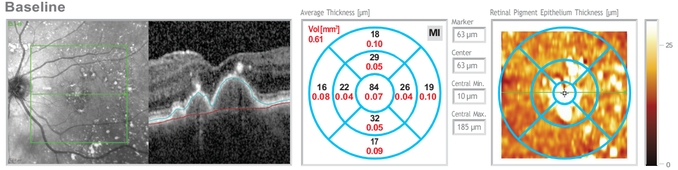
Individual Patient Results

At Month 13, a significant reduction in drusen volume and no visible loss of photoreceptor/retinal pigment epithelium cells were observed.

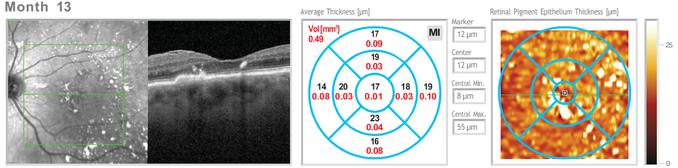
Age: 77 years
Sex: Female

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 trial. 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 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.

Tel: +44 (0) 7871 021 212

Email: lianne.stobo@eyecorrectioncentre.co.uk

Web: www.eyecorrectioncentre.co.uk

VALEDA | EYE CORRECTION CENTRE | LumiThera

CE 2797 | UKCA 0086

VALEDA®
Light Delivery System

EYE CORRECTION CENTRE

The First Approved Treatment for Dry AMD

It's Time for Patients to See Their Future

Now FDA-Authorized

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]

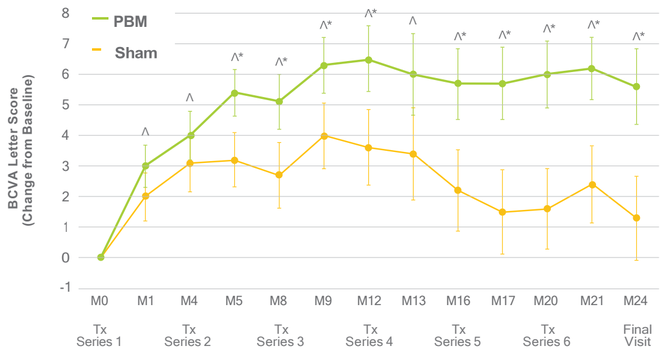
Tx Series 1	Tx Series 2	Tx Series 3	Tx Series 4	Tx Series 5	Tx Series 6	Month 24 Final Visit
PBM	PBM	PBM	PBM	PBM	PBM	
Sham	Sham	Sham	Sham	Sham	Sham	
9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	9 Tx Sessions/ 3-5 Weeks	

[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 trial. 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

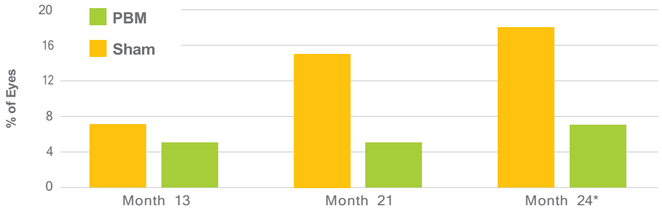
The least squares (LS) mean data using multiple imputation and standard error (SE) are presented. * $p < 0.05$ between group comparison; ^ $p < 0.0001$ within group comparison (PBM)

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

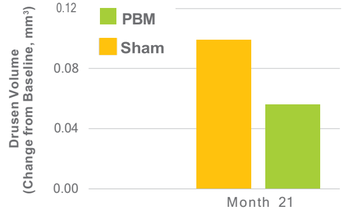
BCVA >5 Letter Loss Over 24 Months*



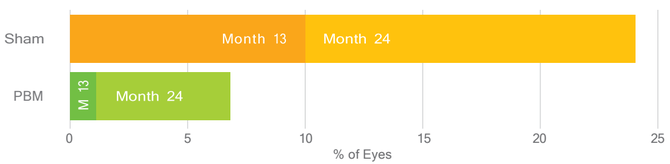
*Number of actual eyes used for percentage of >5 BCVA letter loss at Month 24

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 Sham Group Versus 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)