## First Approved Treatment for Dry Age-Related Macular Degeneration (AMD) Using Photobiomodulation



Light Delivery System **Improves Contrast** Sensitivity

**UALEDA.** 

**Improves** 

Visual Acuity

Mitochondrial Dysfunction and

Oxidative Stress Play a Key Role in

**PBM** 

4H+

**Reduces Central** 

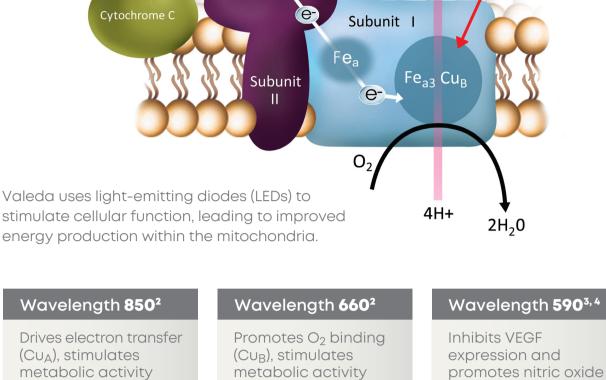
**Drusen Volume** 

# Age-Related Macular Degeneration Mitochondrial cytochrome C oxidase (CCO) is the

primary photoacceptor target for photobiomodulation

Cytochrome C

**PBM** 



(ATP), and inhibits

inflammation and

cell death

1. Jarrett et al., Mol Aspects Med.v33.2012. 2. Wong-Riley et al., J Biol Chem.v280.2005. 3. McDaniel et al., Am Soc Laser Med Surg Mtg. 2006. 4. Ball et al., J Photochem Photobiol B Biol.v102.2012. 5. Munk et al., ARVO online planner: C0081. April 2018. LIGHTSITE I STUDY

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A Double-Masked, Randomized, Sham-Controlled Study

with Photobiomodulation in Dry Age-Related Macular

## **AREDS Category Distribution at Baseline**

10

75

65

0.4

0.2

0.0

Month 12

CS Change from Baseline

Baseline

□ PBM Tx Series 1 □

Degeneration Subjects<sup>5</sup>

**AREDS Category** 20 30 patients, **PBM** 46 eyes (ITT) Sham mber of Eyes 15 • 1:1 treatment (Tx) to

### Tx baseline and repeat at 6m



Month 1

sham distribution

 Tx schedule 3x per week for 3 weeks

Month 7

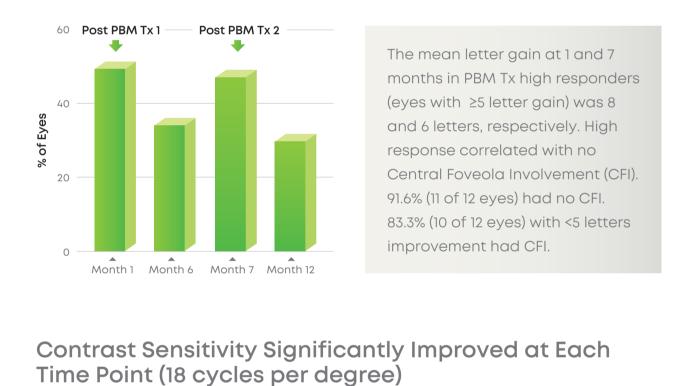
Month 12

# **ETDRS Letter Score** 70

Month 6

Percent of PBM Tx Eyes That Achieved a 5+ Letter Gain

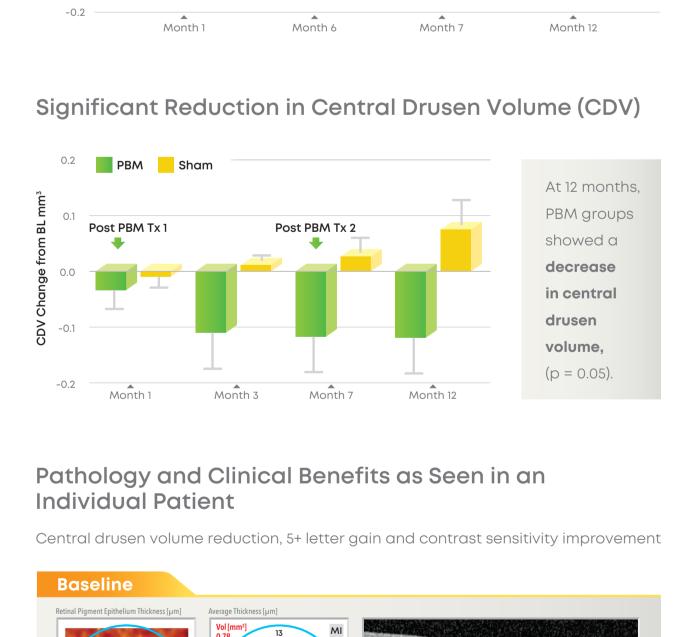
☐ PBM Tx Series 2 ☐



### 0.6 PBM Post PBM Tx 1 Post PBM Tx 2 Sham (\* = p < 0.05)\*

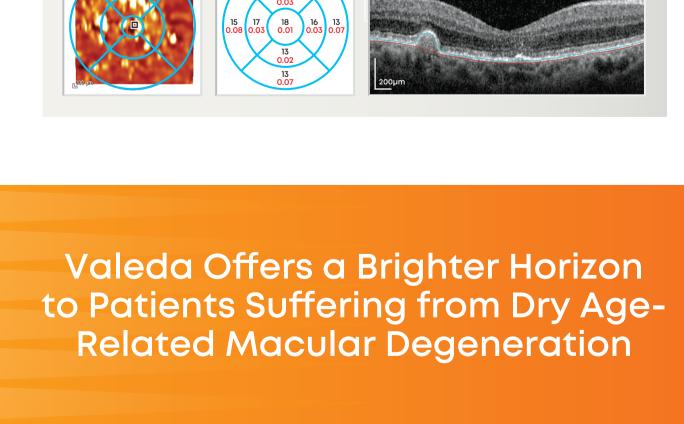
\*

\*



# 76 0.12

MI



### Under the clinician's supervision, trained staff are able to administer the Valeda treatment. Excellent safety profile

Treatments are delivered in a series of 9 sessions per eye over a three-week period. Each treatment session lasts less than 5 minutes per eye.

Preserves future treatment options

Valeda was designed for ease of

use in the clinician's office

Valeda is a platform with the potential to successfully treat a number of degenerative ocular diseases.

**Indications for Use** 

## with degenerative diseases such as dry age-related macular degeneration. MILOFTALMICA



R Only

MKT-0002 Rev A





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

> www.miloftalmica.it info@miloftalmica.it | marketing@miloftalmica.it +39 02 471348

> > www.lumithera.com