Ocuphire PHARMA

Restore Vision & Clarity

Glaucoma & Anterior Segment Eyecelerator@AAO 2021

Mina Sooch CEO and Founder

November 11, 2021

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Ocuphire Overview

A Late-Stage Clinical Ophthalmic Biotech (Nasdaq Symbol: OCUP)

Nyxol®

Presbyopia

U.S. Prevalence: ~128M

Positive Phase 2 Top-line Data 2Q21
Advance Two Phase 3 in 2022

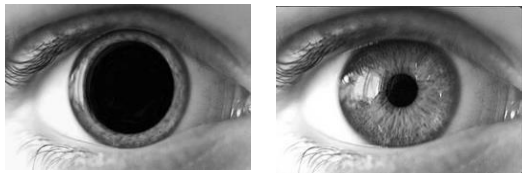
Night Vision Disturbances

U.S. Prevalence: ~16M adults

Phase 3 Recruiting
Phase 3 Top-Line Data early 2022

Reversal of Mydriasis

~100M pupil dilations per year in U.S.



Positive Phase 3 Top-Line Data 1Q21
2nd Phase 3 Planned 2H21
2nd Phase 3 Top-Line Data early 2022
NDA Submission Late 2022

APX3330

Phase 2 Recruiting
Phase 2 Top-Line Data in 2022

Diabetic Retinopathy

U.S. Prevalence: ~ 7M

Diabetic Macular Edema

U.S. Prevalence: ~750K

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2021: The Time for Presbyopia Drops

Headlines From Academia and Industry Articles Thru the Year with an Early First Approval

September 22, 2021 | 11 min read SAVE

Treatment landscape for presbyopia evolving toward noninvasive options

Presbyopia treatment options now and on the horizon

Refractive
September 2021

Clinical Ophthalmology Dovepress

REVIEW

Presbyopia – A Review of Current Treatment Options and Emerging Therapies

New options are on the horizon for presbyopia-correcting drops

August 30, 2021
Dr Marguerite B. McDonald
Ophthalmology Times Europe Journal, Ophthalmology Times Europe September 2021, Volume 17, Issue 07

Presbyopia
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NOVEMBER 2021

FDA APPROVAL OF ABBVIE EYE DROP A NEW MOMENT IN PRESBYOPIA ***10/29/2021***

Presbyopia
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Article

Presbyopia-correcting drops: The next frontier

Pharmaceuticals are poised to enhance near vision for millions of presbyopes.

By Conni Bergmann Koury July 1, 2021

A Review of Pharmacological Presbyopia Treatment

Andrzej Grzybowski, MD, PhD, MBA, Agne Markeviciute, MD†, and Reda Zemaitiene, MD, PhD†*

CLINICAL UPDATE

How Presbyopia Correction Drops Will Change My Treatment Regimen

CRST Cataract & Refractive Surgery Today

"The correction of presbyopia remains ophthalmology's 'Holy Grail'…"

-OIS

Presbyopia-Correcting Eyedrops Move Ahead

Presbyopia Treatment Market Size Projected to Rise Lucratively by 2026 end BioSpace

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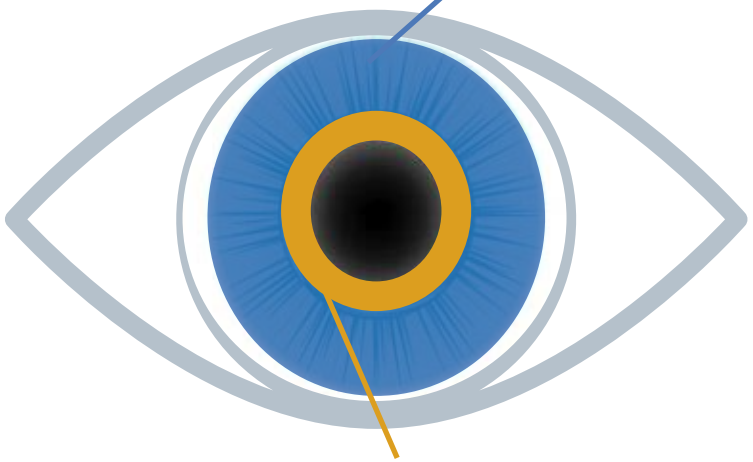
Sources: Academic review articles, journals, and publications

Product Profile: Nyxol® + Low-Dose Pilocarpine (LDP) Combo

Moderate Action on Iris Dilator and Iris Sphincter Muscles for Near Vision Improvement

0.75%Nyxol

Iris Dilator Muscle *Inhibition*



Iris Sphincter Muscle *Activation*

0.4% LDP

Evening drop

- **Phentolamine (alpha1/2 antagonist) approved non-ocular injectable indications decade(s) ago 505(b)(2)**
- **Novel MOA on iris dilator with 24+ hour durability**
- **Moderate 1+mm pupil reduction**
- **No daytime redness w/ chronic evening dosing Nyxol**
- **Well-tolerated with no systemic effects**
- **Stable, preservative-free, single use vial**

1.5 to 2.5 mm PD reduction moves toward the pin-hole (2 to 2.5 mm, up to 3 mm)

Daytime drop

- **Pilocarpine (cholinergic agonist) approved decades ago**
- **Known MOA on sphincter muscle with potent miotic effects at approved doses (1%, 2%, 4%)**
- **Chronic daytime dosing of LDP**
- **Low concentration avoids known tolerability issues:**
  - **headache and browache**
  - **redness**
  - **accommodative spasm causing loss of distance vision especially at night**

Source: 1) Nyxol® data from 8 completed trials; Pilocarpine Product label and Literature

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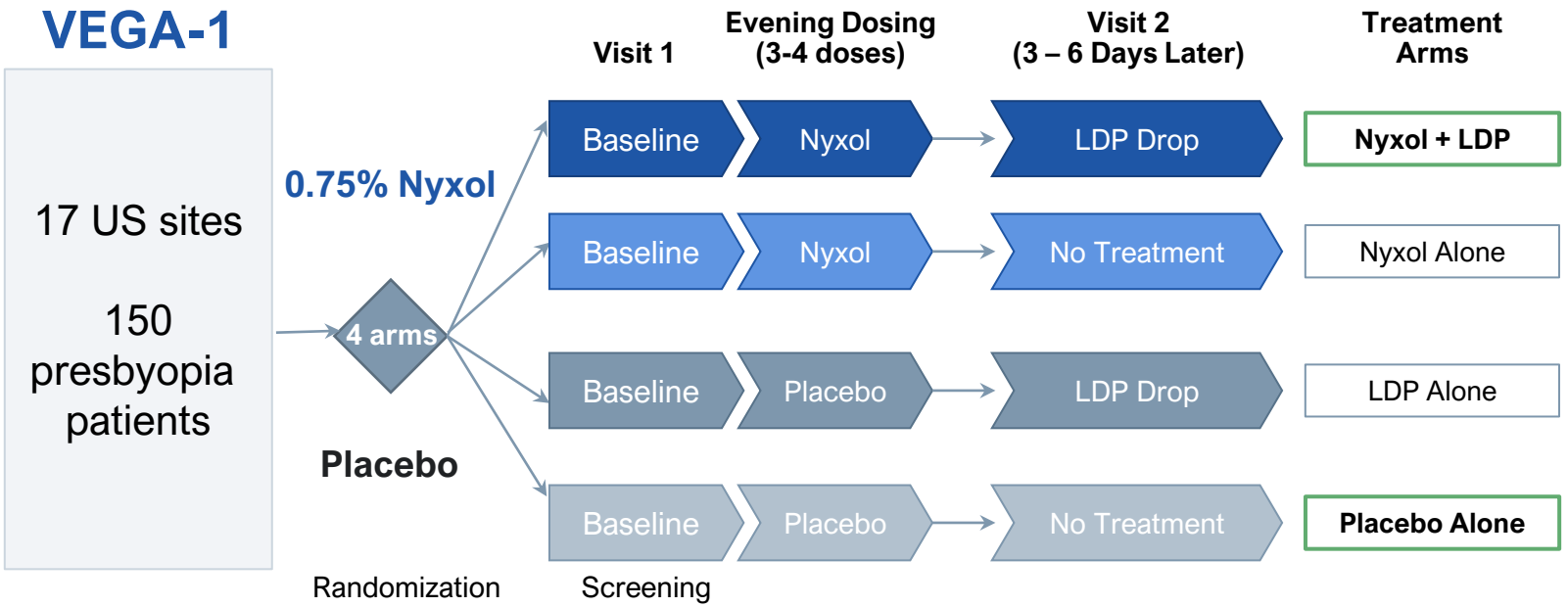
Presbyopia VEGA-1 Phase 2 Design

Randomized, Double-Masked, Placebo-Controlled, Multi-Center One-Week Trial



Eligibility Criteria

- Males or females ≥ 40 and ≤ 64 years of age
- BCDVA of 0.0 LogMAR(20/20 Snellen equivalent) or better in each eye under photopic conditions
- DCNVA of 0.4 LogMAR (20/50 Snellen equivalent) or worse in photopic conditions in each eye & binocularly

Phase 2 Enrollment Completed Feb to May 2021 – 150 Subjects
Reported Topline Results End of 2Q21

Endpoints

Primary: % of subjects with ≥ 3 lines of improvement in distance-corrected near visual acuity comparing Nyxol + LDP vs placebo alone at 1 hour

Secondary:

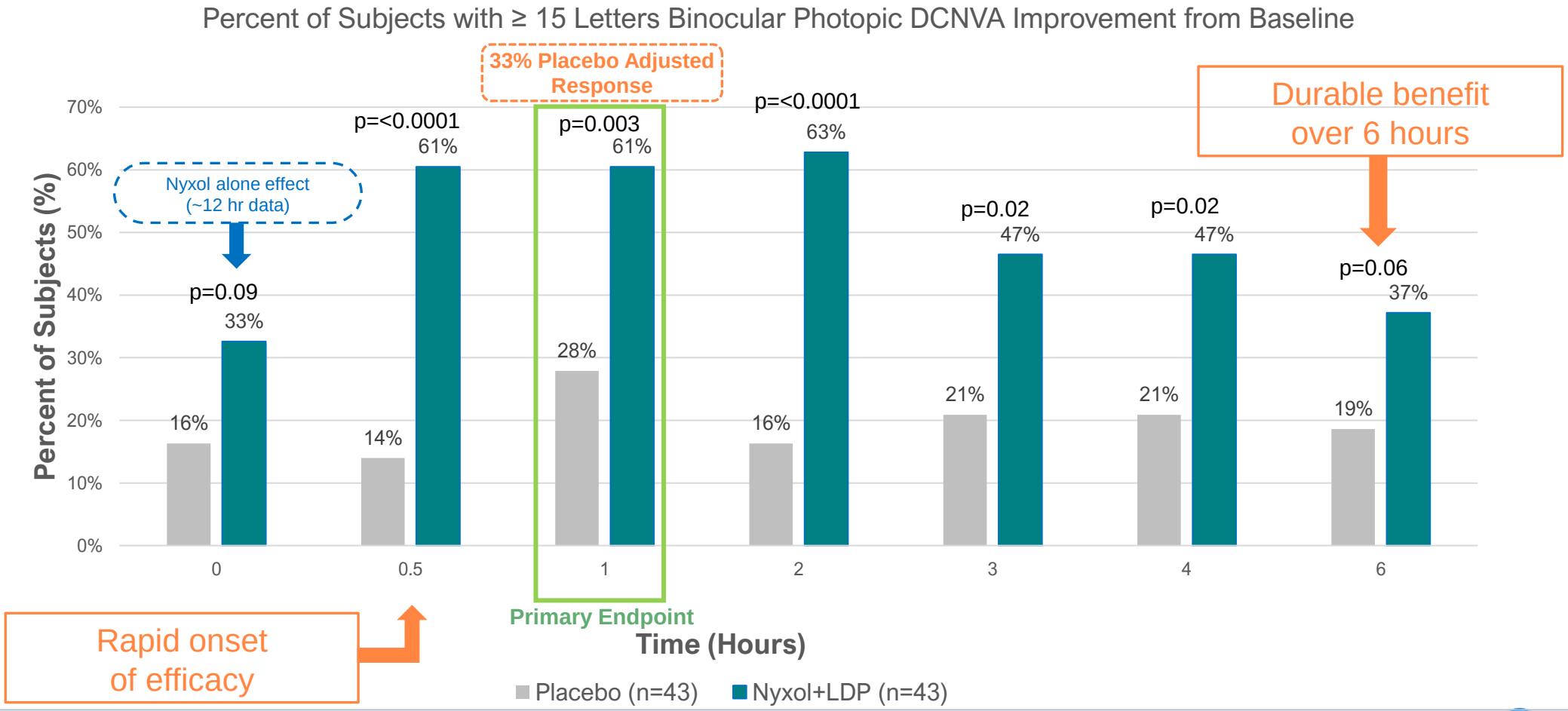
- % of subjects with ≥ 2 and ≥ 3 lines gained at time points from 30 min to 6 hours in photopic lighting comparing Nyxol + LDP vs placebo, Nyxol alone, and LDP alone
- No loss of distance vision
- Pupil diameter at time points
- Safety and tolerability (redness)

Clinical trial NCT#04675151. DCNVA = distance-corrected near visual acuity . BCDVA = best corrected distance visual acuity

Efficacy Endpoints: % of Subjects ≥ 15 Letter DCNVA Gain Across Timepoints

Nyxol + LDP had Strong Response with ≥ 15 Letter Near Gain from 30 Minutes to 6 Hours

VEGA-1 Phase 2 Trial



Source: VEGA-1 TLR Table 14.2.1.2 Percent of Subjects with Improvement From Baseline in Photopic DCNVA by Time Point (PP Population). 15 letters is 3 lines.

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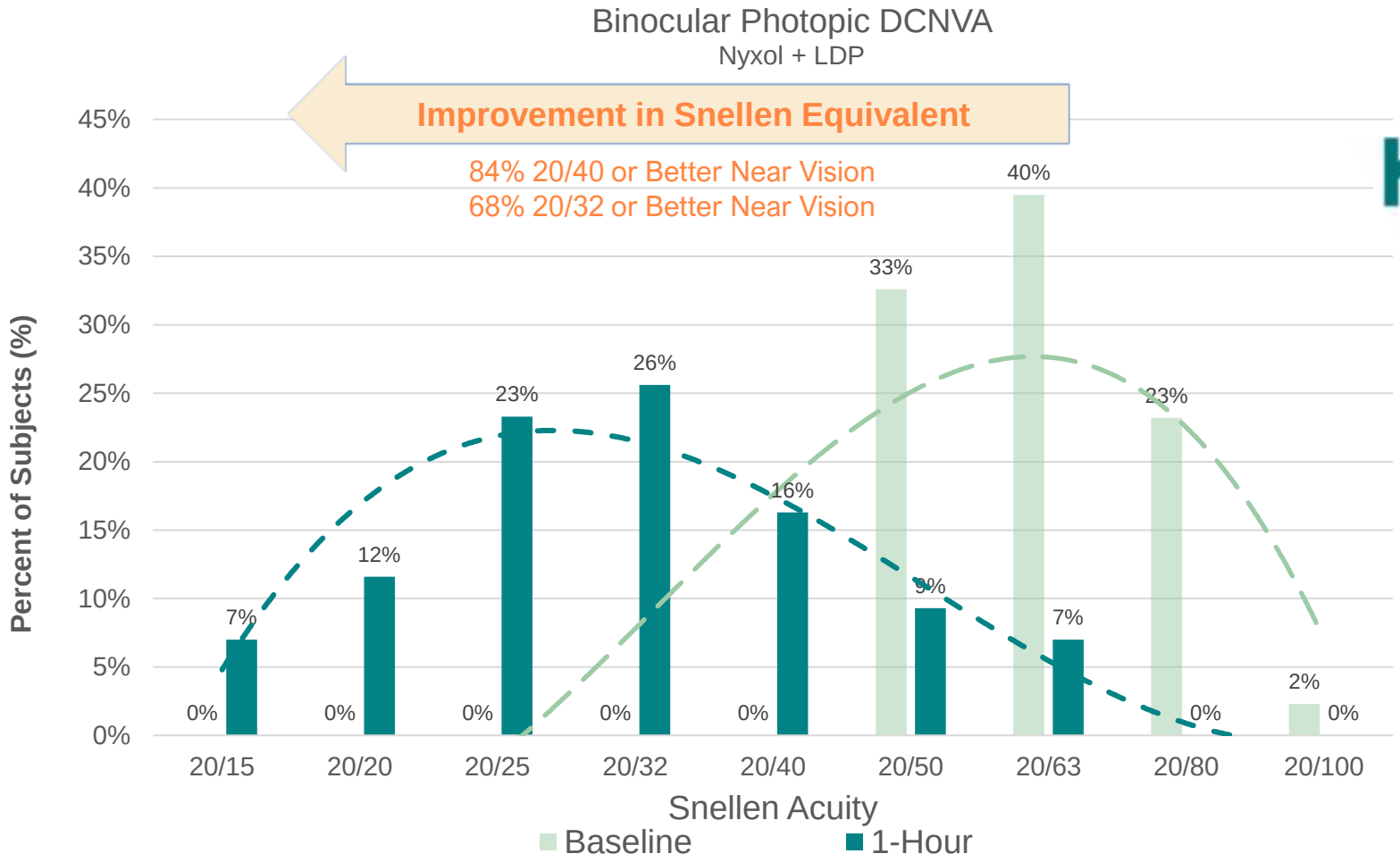
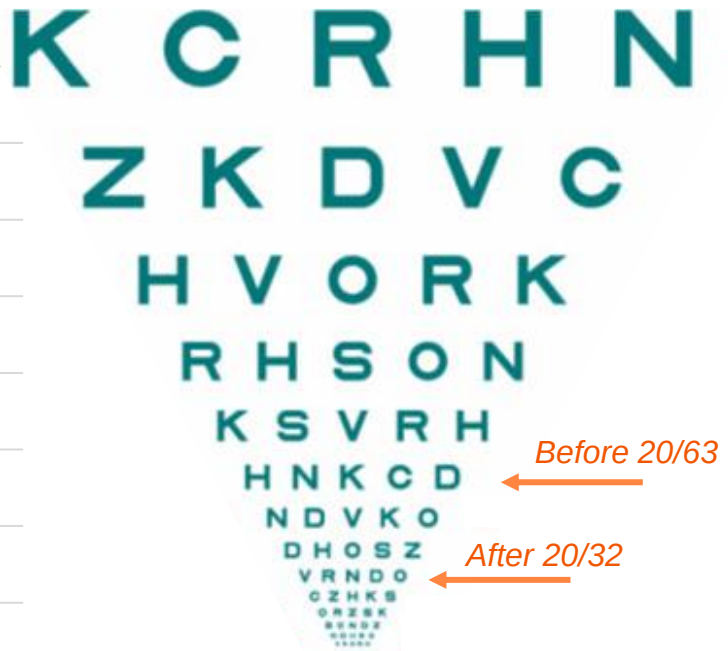
Secondary Endpoint: Improvement in DCNVA Baseline vs. 1 Hour Post Nyxol+LDP

Nyxol + LDP had a Rapid Improvement on Near Vision for Many Patients

VEGA-1 Phase 2 Trial



Visual Acuity Chart



Source: VEGA-1 TLR Table 14.2.24.1 Percent of Subjects with Photopic DCNVA by Time Point (PP Population)

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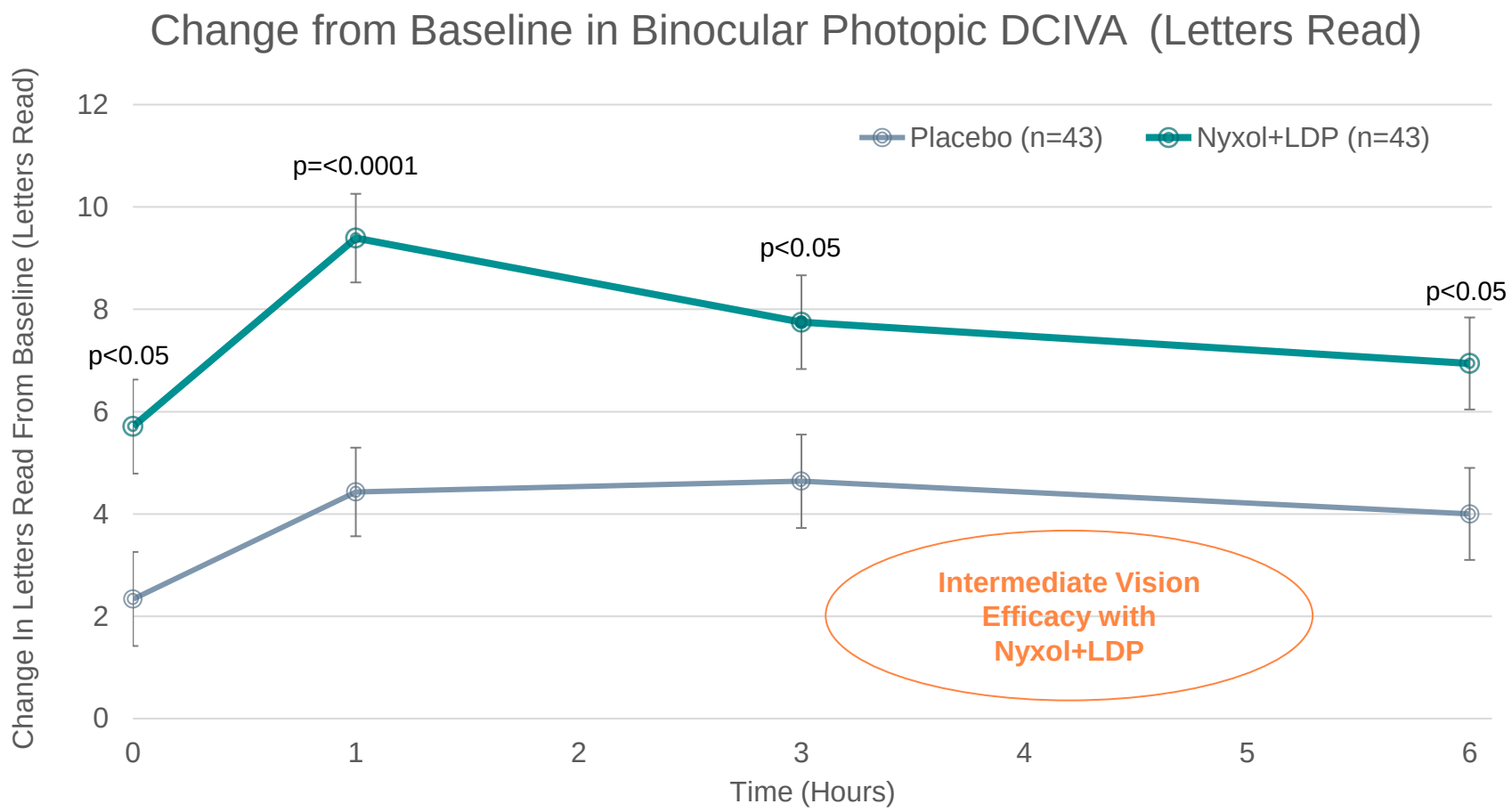
Secondary Endpoint: Intermediate Vision

Nyxol + LDP Had Significant Improvement in Letters Read in DCIVA Compared to Placebo

VEGA-1 Phase 2 Trial



Source: VEGA-1 TLR Table 14.2.7.1 Observed Values and Change from Baseline in Photopic DCIVA by Time Point (Letters Read) (PP Population)

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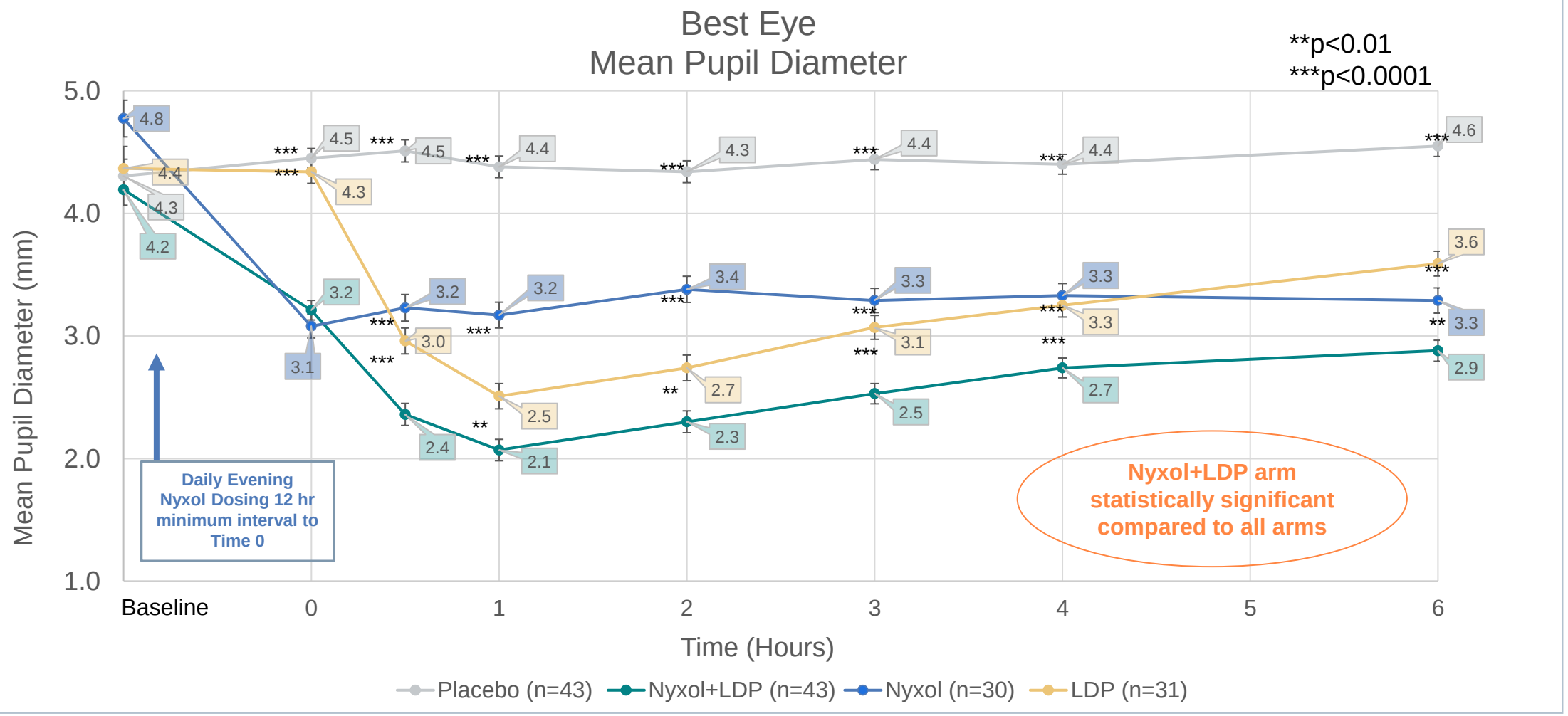
Secondary Endpoint: Mean Pupil Diameter Over Time

Achieved Pupil Size ~2mm in Nyxol+LDP Consistent with 3-line Improvement in Near Vision

VEGA-1 Phase 2 Trial



Source: VEGA-1 TLR Table 14.2.12.1 Observed Values and Change from Baseline in Photopic Pupil Diameter by Time Point (PP Population)

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Additional VEGA-1 Phase 2 Efficacy Results

Nyxol + LDP Efficacy Data has Potential for Differentiation

- **Met the planned Phase 3 primary endpoint of 15 letters (3 lines) near vision gain with less than 5 letters of distance vision loss**
  - Statistical significance and/or trend across multiple timepoints for combination treatment vs. each individual component (Nyxol or LDP)
- **Met multiple additional key secondary endpoints**
  - Nyxol+LDP was numerically better than each component at every timepoint
  - Efficacy data in both light and dark iris colors
  - Near vision efficacy seen monocularly

Source: VEGA-1 Clinical Study Results

Safety Findings

Nyxol + LDP Combination Was Well Tolerated with a Favorable Safety Profile

- No serious AEs, almost all AEs were mild
- **0% headaches or brow aches reported for Nyxol+LDP arm**
- **≤ 5% mild, transient conjunctival hyperemia AEs in Nyxol+LDP arm**
- **No change in distance vision for Nyxol + LDP arm**
  - **0% had ≤ 5 letter distance loss in photopic lighting**
  - **Only 5% distance loss in mesopic lighting**
- No change in IOP

Source: VEGA-1 Study Results (Safety Population, n=150); Only a single subject difference between mITT (n=148) and PP population (n=147)

Summary & Next Steps for Ocuphire Presbyopia Drops

Advance Into Phase 3 with a Differentiated Product Profile

Important Product Attributes	Nyxol+LDP Clinical Data
Efficacy	✓
Safety: Maintain Distance	✓
Safety: Tolerability	✓
Durability	✓
Fast Onset	✓
Convenient Daily Drops	✓
Tunable Pupil Modulation	✓

Ocuphire is differentiated by using both the dilator and sphincter muscles moderately to reach a pin-hole pupil size

AAO 2021 Presentations

AAO Refractive Surgery Day ePoster
VEGA-1 Presbyopia Presentation by Dr. Jay Pepose
Abstract # 30068457

AAO Retina Day Scientific ePoster
ZETA-1 DR/DME Presentation by Dr. Mike Allingham
Abstract # PO332

Advance into Presbyopia Phase 3
With Registration Trials in 1H22
Towards a Potential NDA Filing in 2023

Source: VEGA-1 Clinical Study Results

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