Ocuphire PHARMA

Restore Vision & Clarity

VEGA-1 Phase 2 Topline Results Conference Call

June 30, 2021

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Agenda and Participants

Phase 2 Trial Topline Readout As Planned In 2Q21

- Topline VEGA-1 Phase 2 Clinical Trial Results for Nyxol and Low-Dose Pilocarpine in Presbyopia
- Presbyopia Market Opportunity
- Future Milestones
- Q&A

Participants

Mina Sooch, MBA, President and CEO

Mitch Brigell, PhD, Head of Clinical Development

Jay Pepose, MD, Medical Advisory Board & Corporate Board Member

Susan Benton, Corporate Board Member

Charlie Hoffmann, MBA, VP of Corporate Development and Operations

Amy Rabourn, MAcc, VP of Finance

Ocuphire Pipeline & Upcoming Milestones

Multiple Phase 3 & Phase 2 Clinical Data Readouts Anticipated Over The Next Year

	Product Candidate	Indication	Development Stage				Anticipated Milestones
			Pre-clinical	Phase 1	Phase 2	Phase 3	
Ocuphire-Focused Development	0.75% Nyxol® Eye Drop	Reversal of Mydriasis (RM)			Positive Data Readout		Initiated Phase 3 MIRA-2 trial 4Q20; Topline data reported in 1Q21 (n=185)
							Initiate Phase 3 MIRA-3 trial 2H21; Data expected in early 2022 (n=330)
							Initiate Pediatric trial 2H21; Data expected in early 2022 (n=20)
	0.75% Nyxol® Eye Drop	Dim Light or Night Vision Disturbances (NVD)					Initiated Phase 3 LYNX-1 trial 4Q20; Data expected in 3Q21 (n=160)
	0.75% Nyxol® + Low-Dose 0.4% Pilocarpine Eye Drops	Presbyopia (P)			Positive Data Readout		Initiated Phase 2 VEGA-1 trial 1Q21; Topline data reported in 2Q21 (n=150)
	APX3330 Oral Pill	Diabetic Retinopathy (DR)/ Macular Edema (DME)					Initiated Phase 2 ZETA-1 trial Apr21; Data expected by early 2022 (n=100)
Partnering-Focused Development	APX2009 Intravitreal	DME, Wet Age-Related Macular Degeneration (wAMD)					Next steps: IND enabling studies (with partner funding)

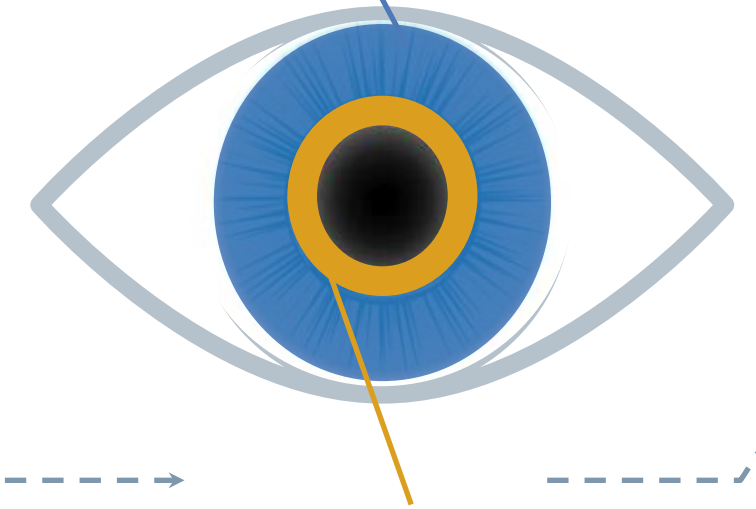
Note: 0.75% Nyxol (Phentolamine Ophthalmic Solution) is the same as 1% Nyxol (Phentolamine Mesylate Ophthalmic Solution)

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

Moderate Use of Iris Dilator And Iris Sphincter Muscles To Improve Near Vision

0.75%Nyxol

Iris Dilator Muscle Inhibition



0.4% LDP

Iris Sphincter Muscle Activation

- **Active ingredient approved decades ago 505(b)(2)**
- **Novel MOA on iris dilator with 24+ hour durability with moderate 1+mm pupil reduction**
- **Chronic daily dosing of Nyxol at bedtime demonstrated no daytime redness**
- **Well-tolerated with no systemic effects**
- **Stable, preservative-free, single use vial**

- **Active ingredient approved decades ago 505(b)(2)**
- **Known MOA on sphincter muscle with more potent miotic effects at approved doses (1%, 2%, 4%)**
- **Chronic daily dosing in daytime**
- **Low concentration avoids known tolerability issues:**
  - **headache and browache**
  - **redness**
  - **accommodative spasm causing loss of distance vision especially at night**

Source: Ocuphire Clinical Trials (completed)

Potential ‘Best in Class’ Presbyopia Drop

Topline Results From Vega-1 Were Positive…

Nyxol + LDP Presbyopia Treatment is Differentiated:

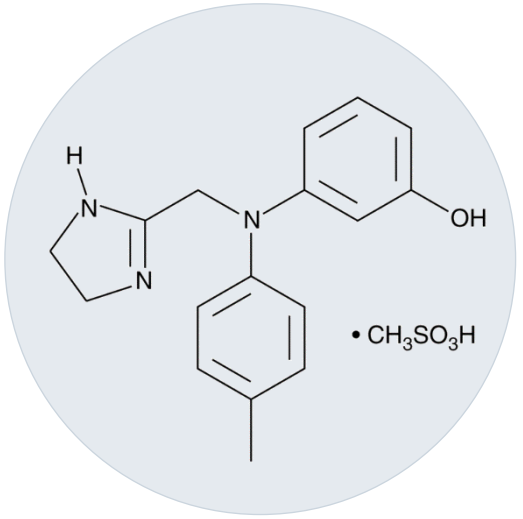
- ✓ **Statistically significant efficacy data**
- ✓ **Favorable safety profile**
- ✓ **Comfort and tolerability**
- ✓ **Fast onset**
- ✓ **Long duration**
- ✓ **Maintain good distance visual acuity (night/day)**
- ✓ **Novel tunable pupil modulation**

Nyxol®

RM Reversal of Mydriasis

NVD Night Vision Disturbances

P Presbyopia



Phentolamine Mesylate

Topline VEGA-1 Phase 2 Results

Randomized, Multi-Center, Double-Masked, Placebo-Controlled Study of the Safety and Efficacy of Nyxol (0.75% Phentolamine Ophthalmic Solution) + 0.4% Low Dose Pilocarpine (LDP) for the Treatment of Presbyopia

Clinical trial NCT#04675151

Objectives and Key Eligibility Criteria

VEGA-1 (OPI-NYXP-201) Phase 2 Trial Evaluating Nyxol + LDP for Treatment of Presbyopia

Key Objectives

PRIMARY

- To evaluate the efficacy of Nyxol + LDP to improve DCNVA compared to Placebo alone in presbyopia subjects

KEY SECONDARY

- To evaluate the ocular and systemic safety of Nyxol + LDP and each component individually
- To evaluate multiple secondary visual acuity and pupil diameter endpoints

Key Eligibility Criteria

INCLUSION

- Males or females ≥ 40 and ≤ 64 years of age.
- BCDVA of 20/20 or better under photopic conditions
- DCNVA of 20/50 or worse under photopic conditions
- Binocular best-corrected near VA is 20/25 or better

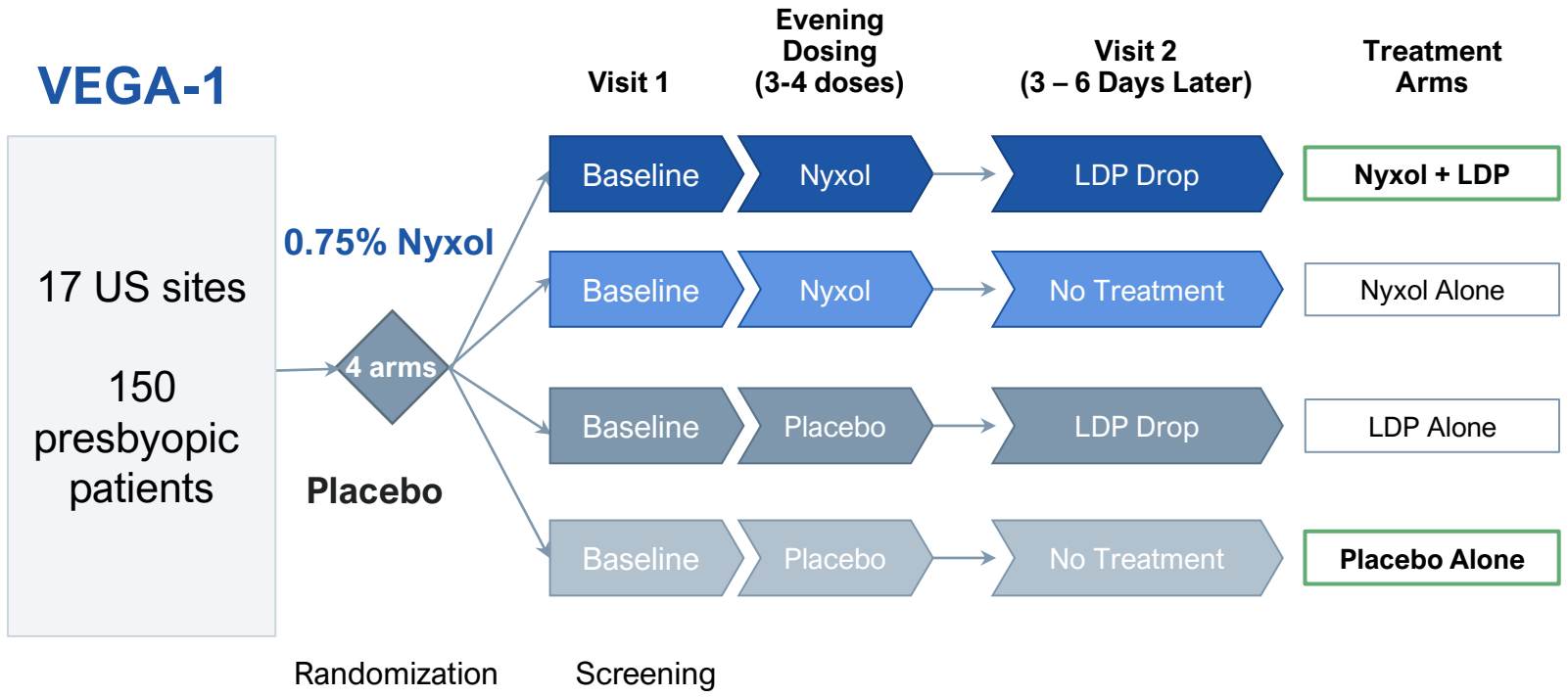
EXCLUSION

- Clinically significant ocular disease
- Recent or current evidence of ocular infection or inflammation in either eye

Clinical trial NCT#04675151. BCDVA is Best Corrected Distance Visual Acuity and DCNVA is Distance Corrected Near Visual Acuity

Presbyopia VEGA-1 Phase 2 Design

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



Phase 2 Enrollment Completed Feb to May 2021 – 150 Subjects

Reporting Topline Results as Guided by 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 and mesopic 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

Patient Population – Subject Disposition

Per Protocol Population, mITT, And Safety Population Are Essentially Identical

	Placebo Alone N (%)	Nyxol Alone N (%)	LDP Alone N (%)	Nyxol+LDP N (%)	Total N (%)
All Randomized Population (ARP)	45	30	31	44	150
Safety Population (SP)	45 (100%)	30 (100%)	31 (100%)	44 (100%)	150 (100%)
Modified Intention to Treat Population (mITT)	44 (98%)	30 (100%)	31 (100%)	43 (98%)	148 (99%)
Per Protocol Population (PP)	43 (96%)	30 (100%)	31 (100%)	43 (98%)	147 (98%)
Completed Study	*44 (98%)*	*30 (100%)*	*31 (100%)*	*43 (98%)*	*148 (99%)*
Discontinued Study Early	*1 (2%)*	*0*	*0*	*1 (2%)*	*2 (1%)*

- 148/150 subjects completed the study (mITT)
- Only a single subject difference between mITT and PP population
- Per Statistical Analysis Plan, all analyses performed on PP population with results being nearly identical for mITT

Source: VEGA-1 TLR Table 14.1.1 Subject Disposition

Demographics (PP Population)

Treatment And Placebo Arms Were Balanced In This Phase 2 Clinical Trial

	Placebo Alone N=43	Nyxol Alone N=30	LDP Alone N=31	Nyxol+LDP N=43	Total N=147
Age (years): Median (Range)	52 (42-62)	54 (41-60)	52 (44-64)	53 (43-63)	53 (41-64)
Sex: Male n (%) **Female** n (%)	15 (35%) 28 (65%)	7 (23%) 23 (77%)	13 (42%) 18 (58%)	5 (12%) 38 (88%)	40 (27%) 107 (73%)
Race: White n (%) **African American** n (%) **Asian** n (%) **Other*** n (%)	37 (86%) 4 (9%) 2 (5%) 0 (0%)	26 (87%) 0 (0%) 0 (0%) 1 (3%)	28 (90%) 1 (3%) 6 (6%) 1 (3%)	40 (93%) 0 (0%) 6 (6%) 0 (0%)	131 (89%) 3 (2%) 11 (5%) 2 (1%)
Dark Iris Color: n (%)	18 (42%)	12 (40%)	12 (39%)	18 (42%)	60 (41%)
Light Iris Color: n (%)	25 (58%)	18 (60%)	19 (61%)	25.1 (58%)	87 (59%)

** includes American Indian or Alaska Native; Native Hawaiian or Other Pacific Islander*

Source: VEGA-1 TLR Table 14.1.2.2 Demographics and Baseline Characteristics (PP Population)

Baseline Characteristics Study Eye (PP Population)

Treatment Arms Were Balanced Across Key Ocular Measurements

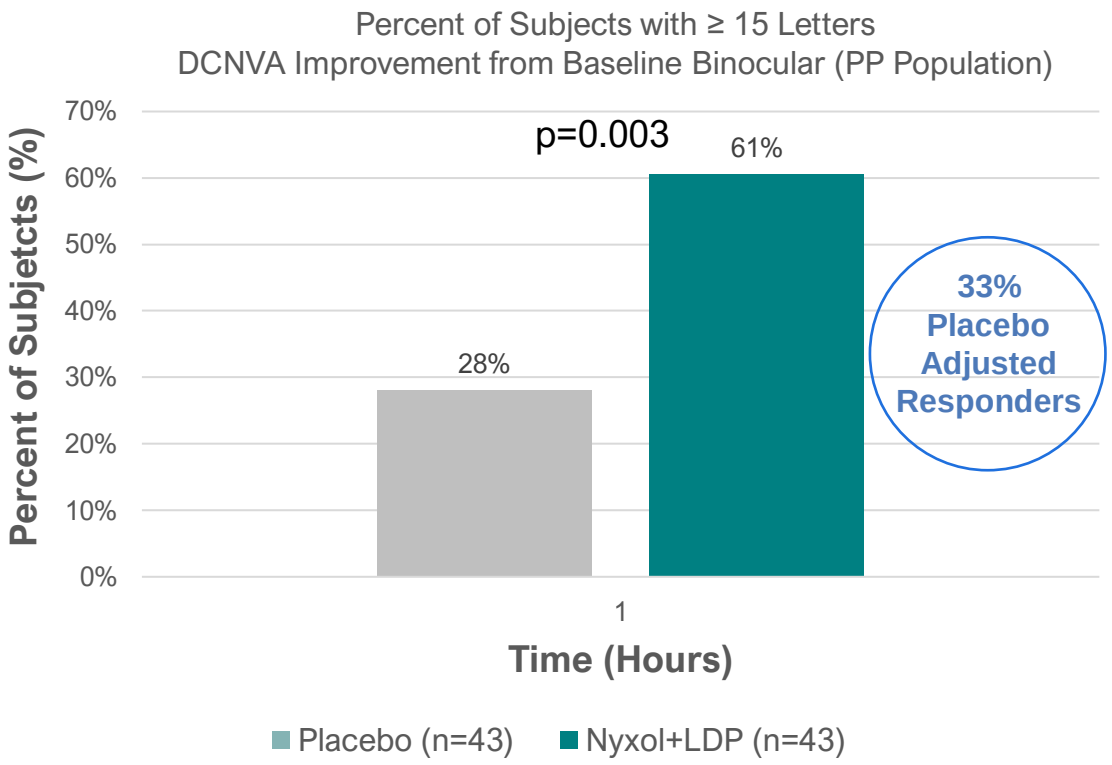
	Placebo Alone N=43	Nyxol Alone N=30	LDP Alone N=31	Nyxol+LDP N=43	Total N=147
Baseline Characteristic					
Photopic DCNVA Mean Letters read-Binocular ***(Snellen Equiv.)*** *70 letters = 20/20*	46 (20/63)	45 (20/63)	48 (20/63)	46 (20/63)	46 (20/63)
Photopic BCDVA Mean Letters read-Binocular ***(Snellen Equiv.)*** *55 letters = 20/20*	62 (20/15)	61 (20/15)	60 (20/15)	61 (20/15)	61 (20/15)
Photopic Pupil Diameter Mean (mm)	4.3	4.5	4.3	4.3	4.3
Mesopic Pupil Diameter Mean (mm)	5.1	5.0	5.0	5.1	5.1
IOP (mmHg)	13.5	14.8	13.9	14.4	14.1

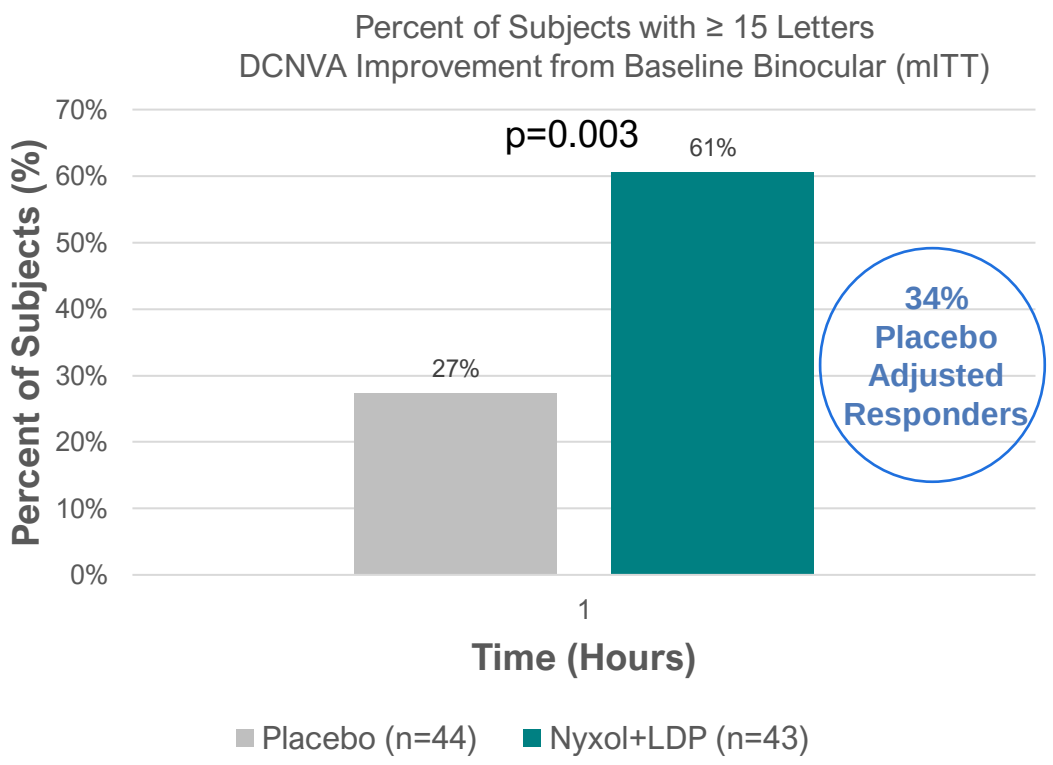
Source: VEGA-1 TLR Table 14.1.2.2 Demographics and Baseline Characteristics (PP population). Snellen Conversion Chart.

Primary Endpoint: % of Subjects ≥ 15 Letter Gain in Photopic DCNVA at 1 Hour

Primary Endpoint Was Met For Nyxol + LDP Gaining ≥ 15 Letters Near Vision In PP Population

VEGA-1 Phase 2 Trial



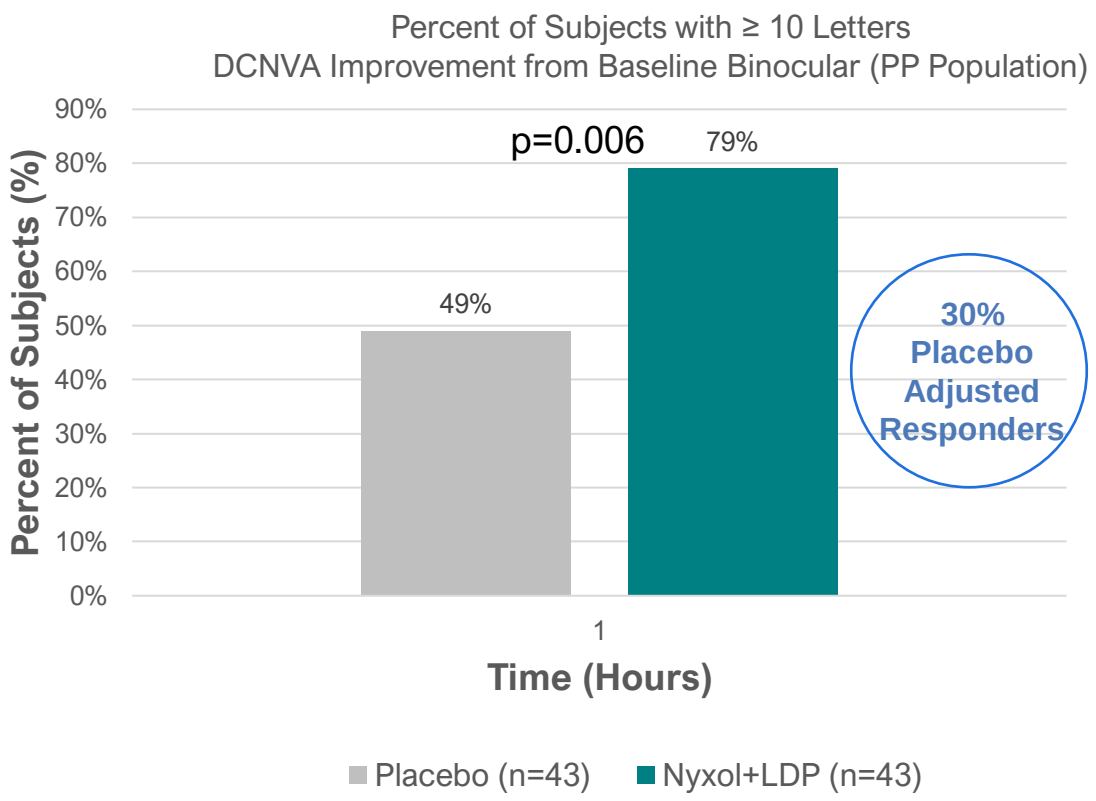


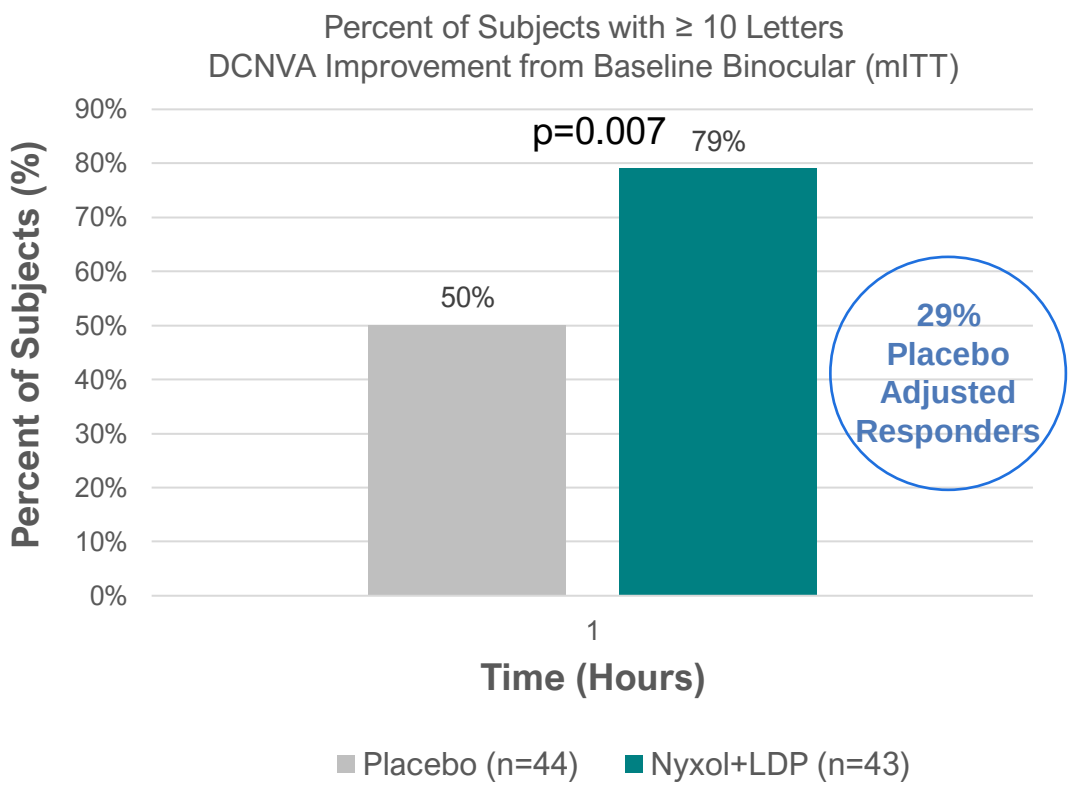
Source: VEGA-1 TLR *Table 14.2.1.1 (mITT) and 14.2.1.2 (PP)Percent of Subjects With Improvement From Baseline in Photopic DCNVA by Time Point . 15 letters is 3 lines.*

Secondary Endpoint: % of Subjects ≥ 10 Letter Gain In Photopic DCNVA At 1 Hour

Many Subjects Treated With Nyxol + LDP Gained A Clinically Meaningful ≥ 10 Letters

VEGA-1 Phase 2 Trial



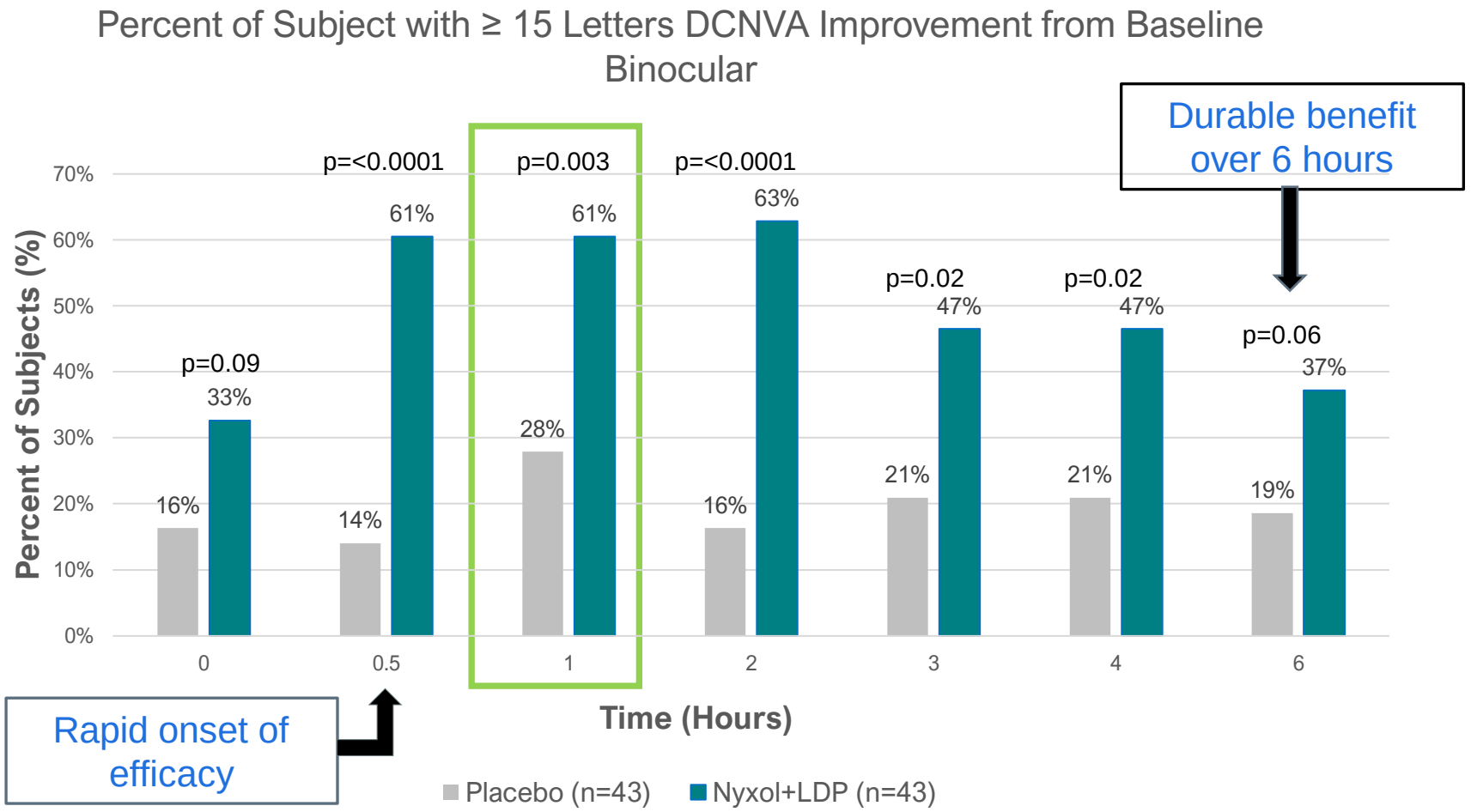


Source: VEGA-1 TLR Table 14.2.1.1 (mITT) and 14.2.1.2 (PP) Percent of Subjects With Improvement From Baseline in Photopic DCNVA by Time Point. 10 letters is 2 lines.

Secondary Endpoint: % of Subjects ≥ 15 Letter Gain At All Timepoints

Nyxol + LDP Had Strong Response With ≥ 15 Letter Gain From 30 Min To 6 Hours

VEGA-1 Phase 2 Trial

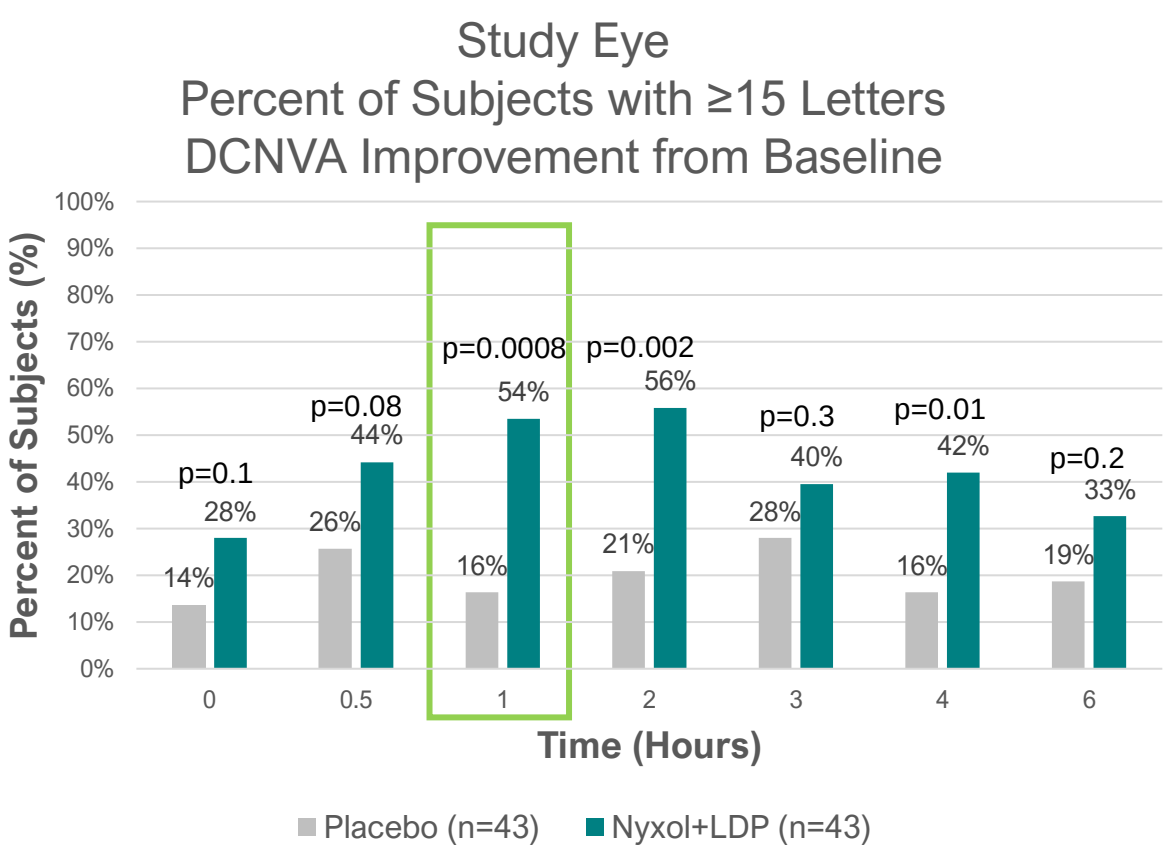


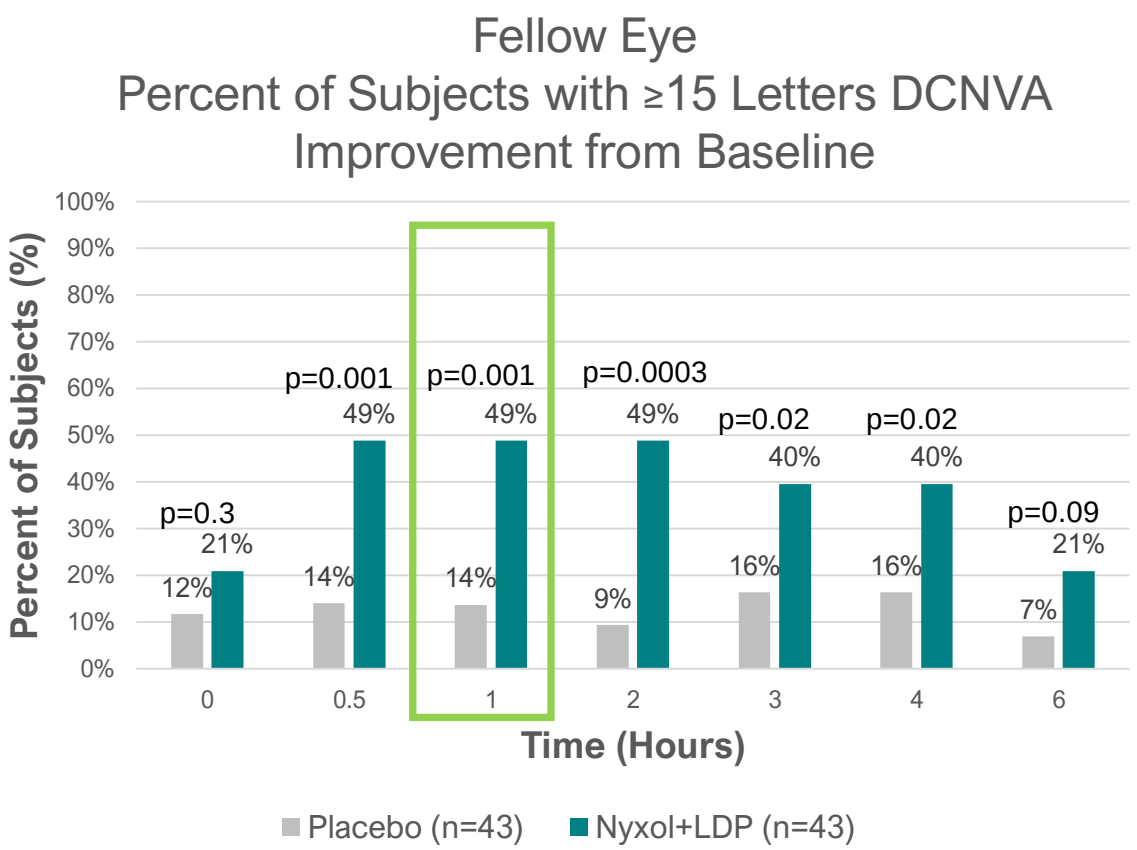
Source: VEGA-1 TLR Table 14.2.1.2 Percent of Subjects with Improvement From Baseline in Photopic DCNVA by Time Point (PP Population). 15 letters is 3 lines.

Secondary Endpoint: % of Subjects ≥ 15 Letter Gain DCNVA (Monocular)

Similar Results Were Seen Monocularly For Study Eye And Fellow Eye On Primary Endpoint

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)

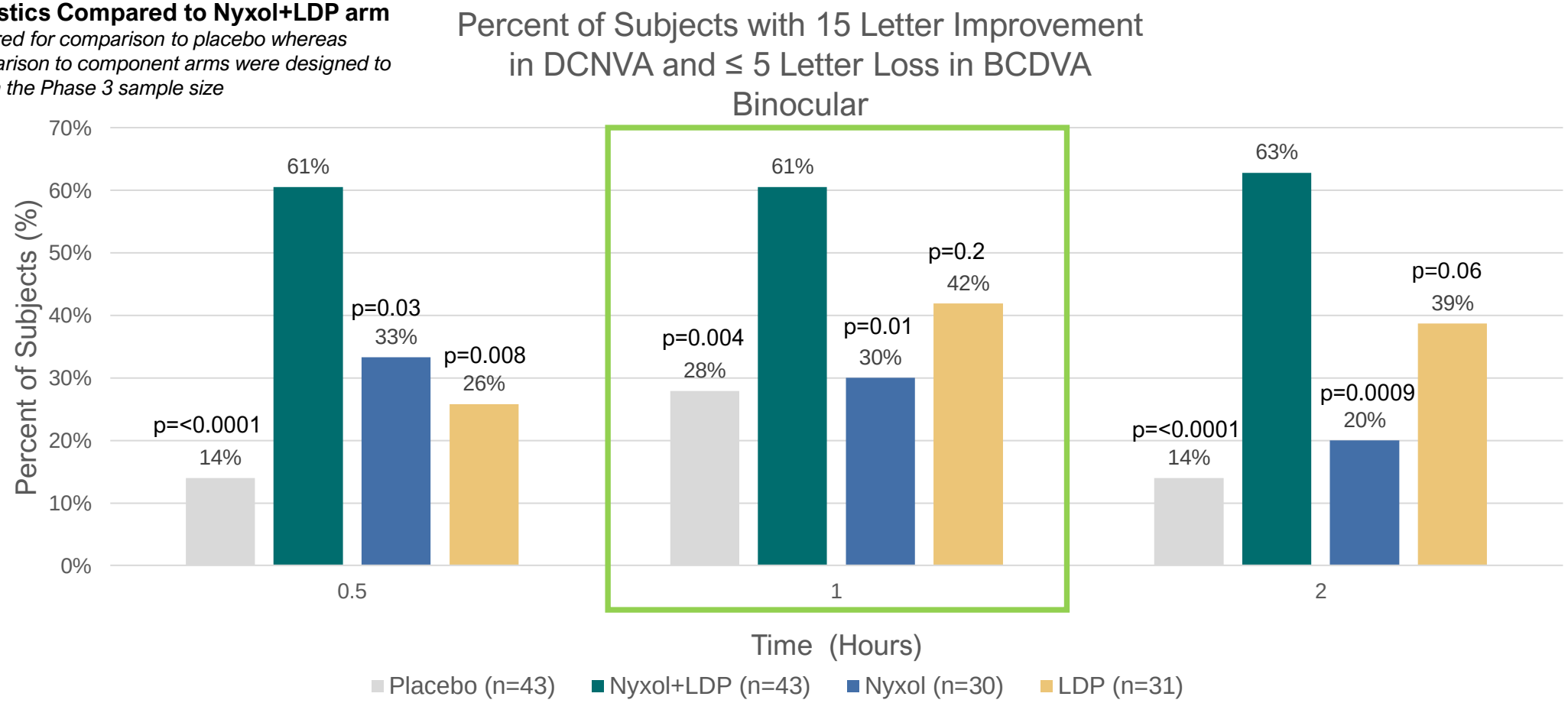
2nd Endpoint: % of Subjects ≥ 15 Letter Gain In Near & ≤ 5 Letter Loss In Distance

Phase 3 Approval Endpoint Also Showed Early Onset Of Near Vision Gain Without Loss of Distance

VEGA-1 Phase 2 Trial

Statistics Compared to Nyxol+LDP arm

Powered for comparison to placebo whereas comparison to component arms were designed to inform the Phase 3 sample size

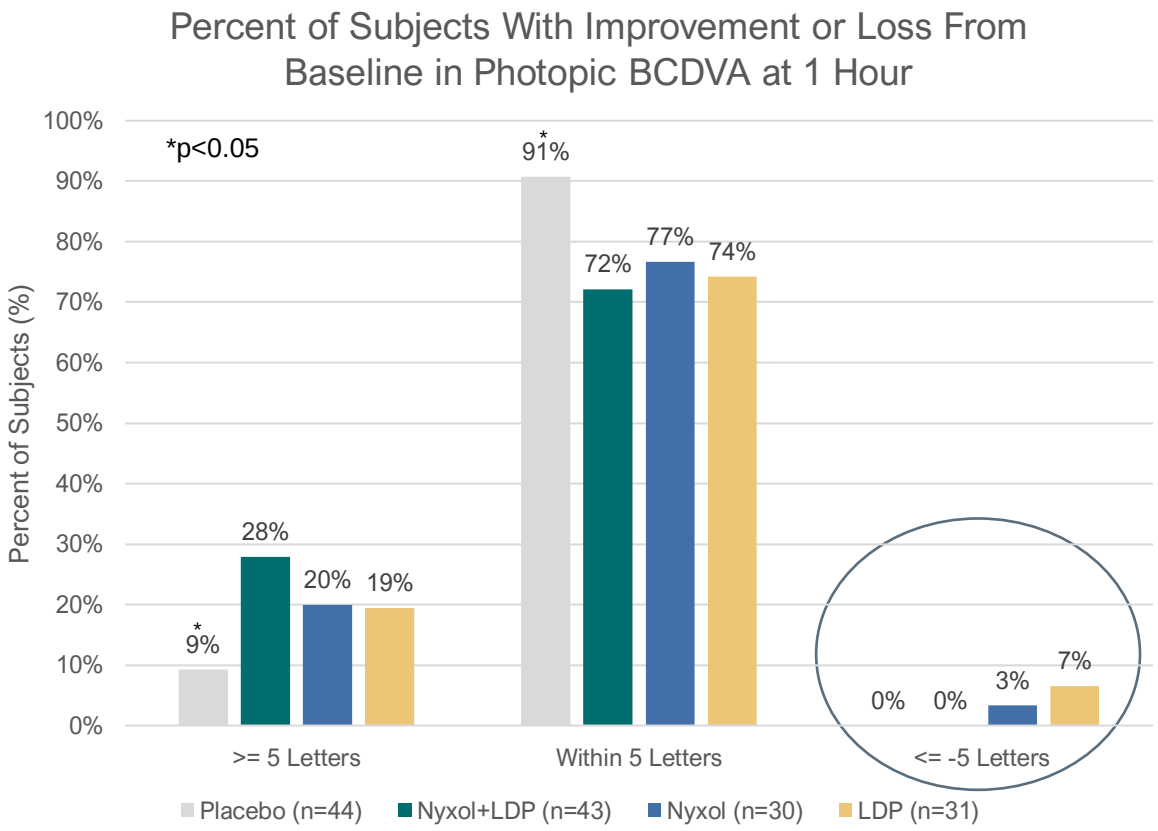


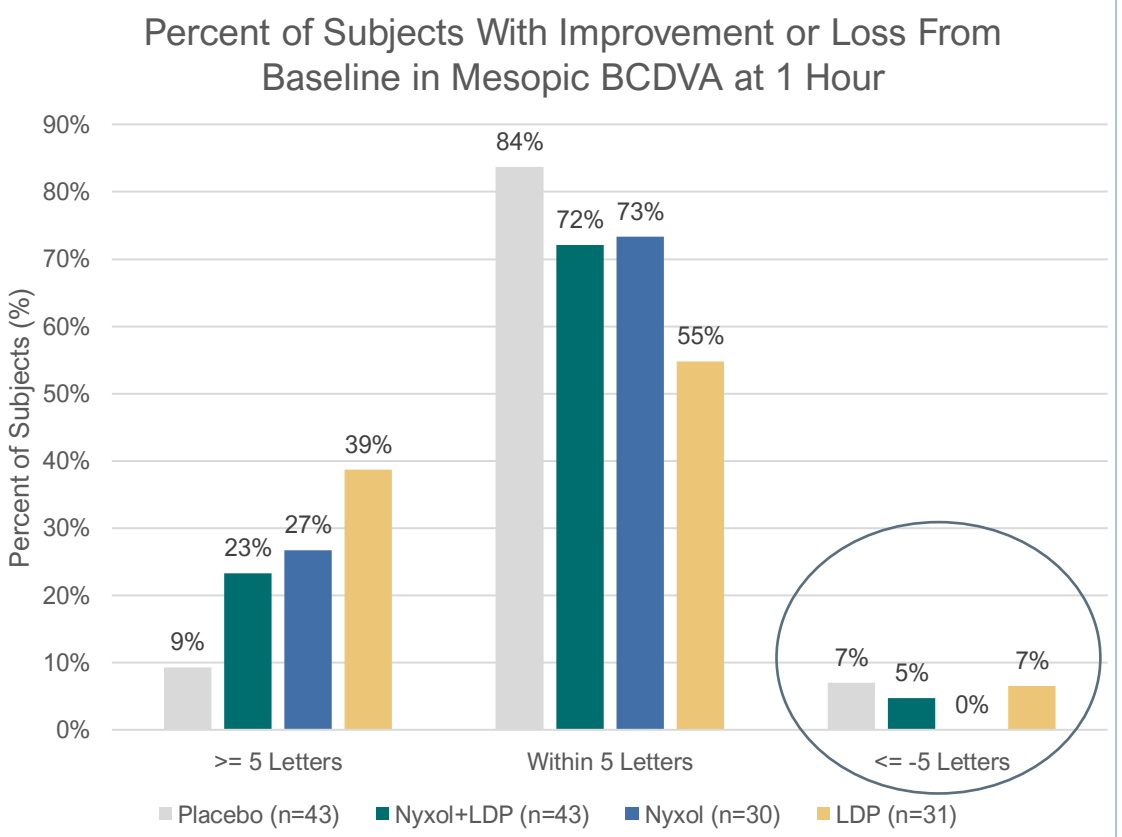
Source: VEGA-1 TLR Table 14.2.2.2 Percent of Subjects with >= 15 Letters of Improvement in Photopic DCNVA and < 5 Letters of Loss in Photopic Binocular BCDVA by Time Point (PP Population)

Change in Photopic and Mesopic BCDVA at the 1-Hour Timepoint

Treatment With Nyxol And/Or LDP Did Not Reduce BCDVA And Had A Modest Beneficial Effect

VEGA-1 Phase 2 Trial

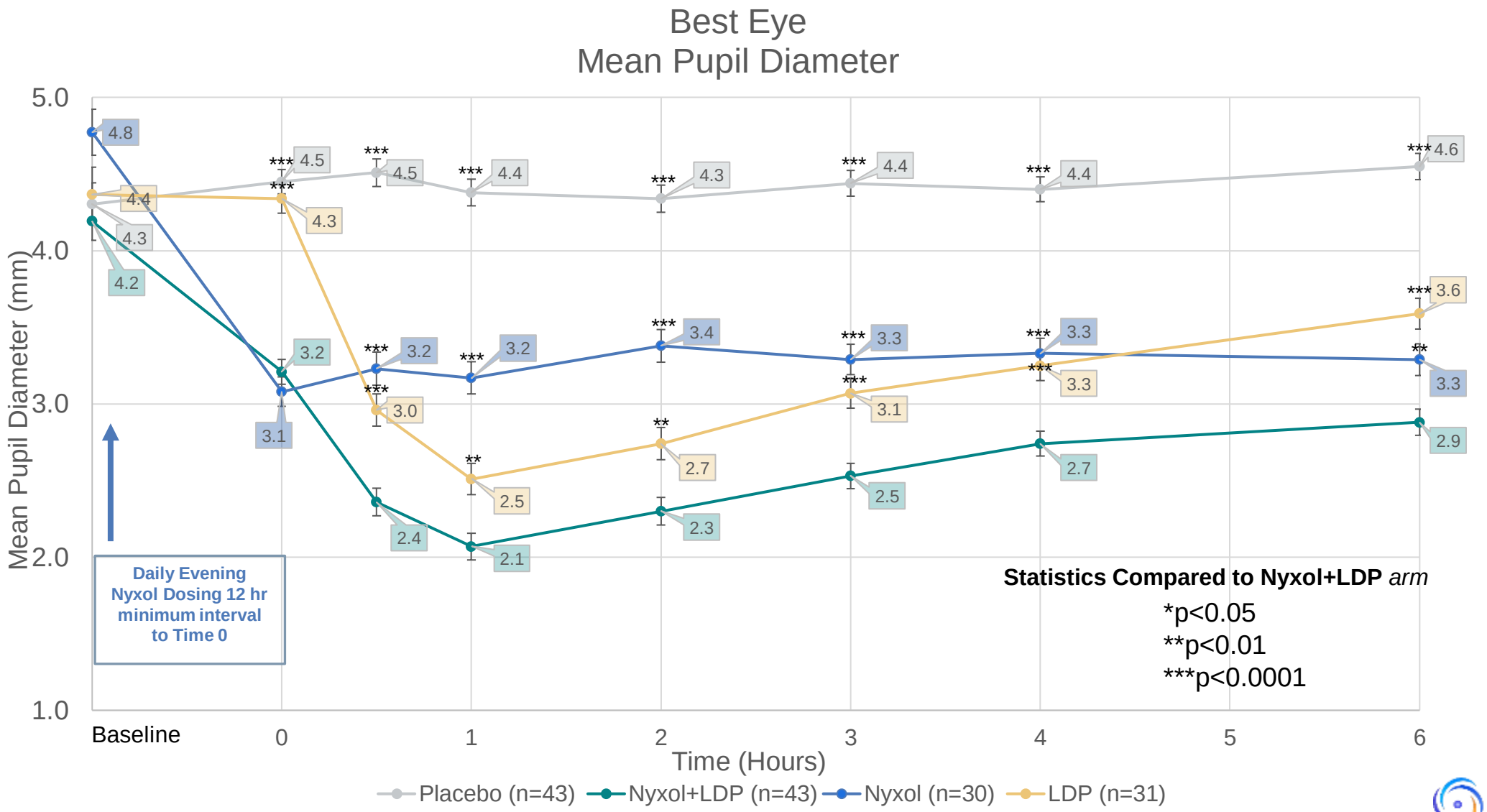




Source: VEGA-1 TLR Table 14.2.8.1 and 14.2.10.1 Percent of Subjects With Improvement or Loss From Baseline in Photopic and Mesopic BCDVA by Time Point (PP)

Secondary Endpoint: Mean Pupil Diameter Over Time

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



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

Secondary Endpoint: Safety Findings

Nyxol+LDP Combination Was Well Tolerated With A Favorable Safety Profile In VEGA-1 Trial

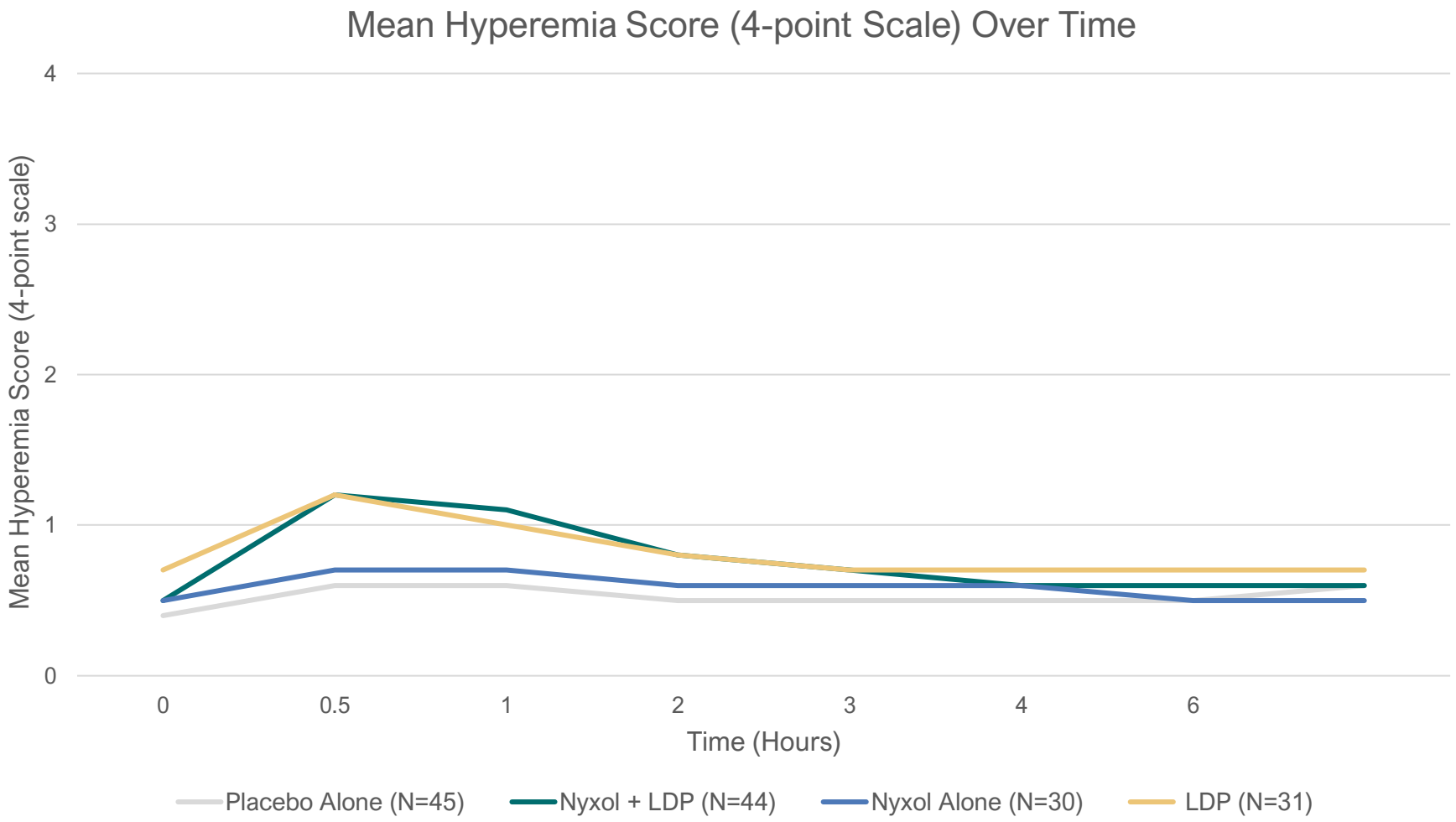
	Placebo Alone n=45	Nyxol Alone n=30	LDP Alone n=31	Nyxol+LDP n=44
Total Treatment Emergent Adverse Events (n)	4	18	13	**50**
TEAEs by Severity (n [%])				
Mild	1 (2.2%)	6 (20%)	6 (19.4%)	**13 (29.5%)**
Moderate	1 (2.2%)	0 (0%)	0 (0%)	**1 (2.3%)**
Severe	0 (0%)	0 (0%)	0 (0%)	**1 (2.3%)**
AEs Occurring in ≥ 5% of subjects (n [%])				
Instillation Site Pain (Mild)	1 (2.2%)	3 (10%)	0 (0%)	**4 (9.1%)**
Instillation Site Erythema (Mild)	0 (0%)	3 (10%)	2 (6.5%)	**5 (11.4%)**
Conjunctival Hyperemia (Mild)	0 (0%)	2 (6.7%)	0 (0%)	**2 (4.5%)**
Eye Disorders (Mild)	1 (2.2%)	2 (6.7%)	4 (12.9%)	**5 (11.4%)**

- No deaths, no serious AEs, and 1 withdrawal due to AEs (on Nyxol alone)
- **0% Headaches or Browaches reported for Nyxol+LDP and Nyxol alone**
- Only 1 subject in LDP alone arm reported mild headache
- Almost all AEs were mild and most common was mild instillation site discomfort
- **Distance visual acuity not adversely affected (as shown earlier)**
- No change in IOP

Source: VEGA-1 TLR Table 14.3.1.1 Overall Summary of Treatment Emergent Adverse Events (TEAE) (Safety Population)
Table 14.3.1.3 Treatment-Emergent Adverse Events (TEAE) by System Organ Class, Preferred Term, and Severity (Safety Population)

Tolerability: Conjunctival Hyperemia (Redness) Score

Minor Change (0.5 Point) In Redness Score Over The First 2 Hours In LDP Arms



Conjunctival Hyperemia CCLRU Scale for Reference

Source: VEGA-1 TLR Table 14.3.3.2 Continuous Summary of Conjunctival Hyperemia by Time Point (Safety Population)

Summary of Positive VEGA-1 Phase 2 Results for Nyxol Eye Drops

Efficacy Data In Subjects With A Favorable Safety Profile In Presbyopia With Nyxol And Low Dose Pilocarpine

- **Met the primary endpoint** with statistical significance for binocular photopic near vision at 1 hour
  - 61% Nyxol + LDP gained 15 letters (3 lines) or more vs. 28% Placebo (33% Placebo Adjusted)
- **Met the Phase 3 co-primary endpoint** vs. placebo gaining 15 letters (3 lines) near vision with less than 5 letters of distance vision loss
- **Met many key secondary endpoints**
  - Rapid onset at 30 min
  - Durable near vision improvement through at least 6 hours
  - Nyxol+LDP was numerically better than each component through 2-hours
  - Sustained significant reduction in PD over at least 18 hours due the durability effects of Nyxol
  - Near vision efficacy seen monocularly and binocularly
  - Also, efficacy data in both light and dark iris colors
- **Favorable safety profile for Nyxol + LDP**
  - No serious AEs
  - No systemic AEs were observed in >5% subjects
  - No headaches, no browaches, and no blurry vision AEs were reported
  - Only mild, transient conjunctival hyperemia observed in <5% of subjects
- **Positive Phase 2 results lead to advancing Phase 3 presbyopia program**

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Next Steps

Ocuphire Plans To Present Full Results At ASCRS In July And Move Into Phase 3

VEGA-1 Presbyopia Presentation by Dr. Pepose at ASCRS on Sunday July 25, 2021 at 8:45am
ASCRS Paper ID 76645 SPS-204 Presbyopia Correcting IOL Comparisons, New Treatments and Studies
MBCR - Level 2, Lagoon EF

MIRA-2 Reversal of Mydriasis Presentation by Dr. Pepose at ASCRS on Monday July 26, 2021 at 4:25pm
ASCRS Paper ID 76599 SPS-316 Corneal Diagnostic Studies
MBCR - Level 2, Lagoon EF

Advance into Phase 3 Presbyopia Registration Trials in 2022 Towards a Potential NDA in 2023

Presbyopia Market Opportunity

Presbyopia – Chronic Opportunity

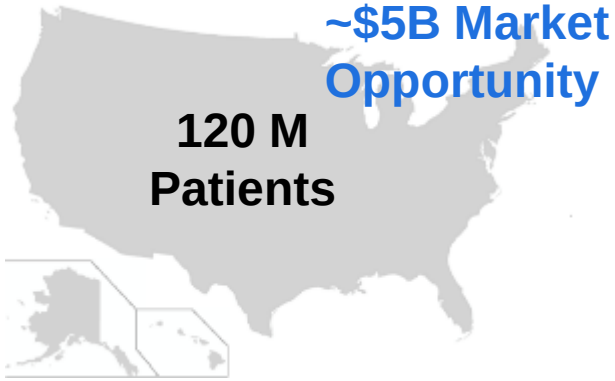
Aging Population Drives Demand for Alternatives to Reading Glasses & Very Large Market

The Problem

- Lens loses ability to change shape when viewing objects up close as we age
- Dependence on reading glasses for intermittent and prolonged use
- Growing need for therapies that improve, rather than hinder, quality of life

> *"Effectively everyone over 40 will have the problems with reading."*
>
> *Physician KOL*

No Currently Approved Drug Therapies



Seeking Treatment Findings	
Patients requesting alternative to reading glasses	40%
Patients would consider an eye drop alternative	69%

Source: GlobalData Market Research Report, 2020

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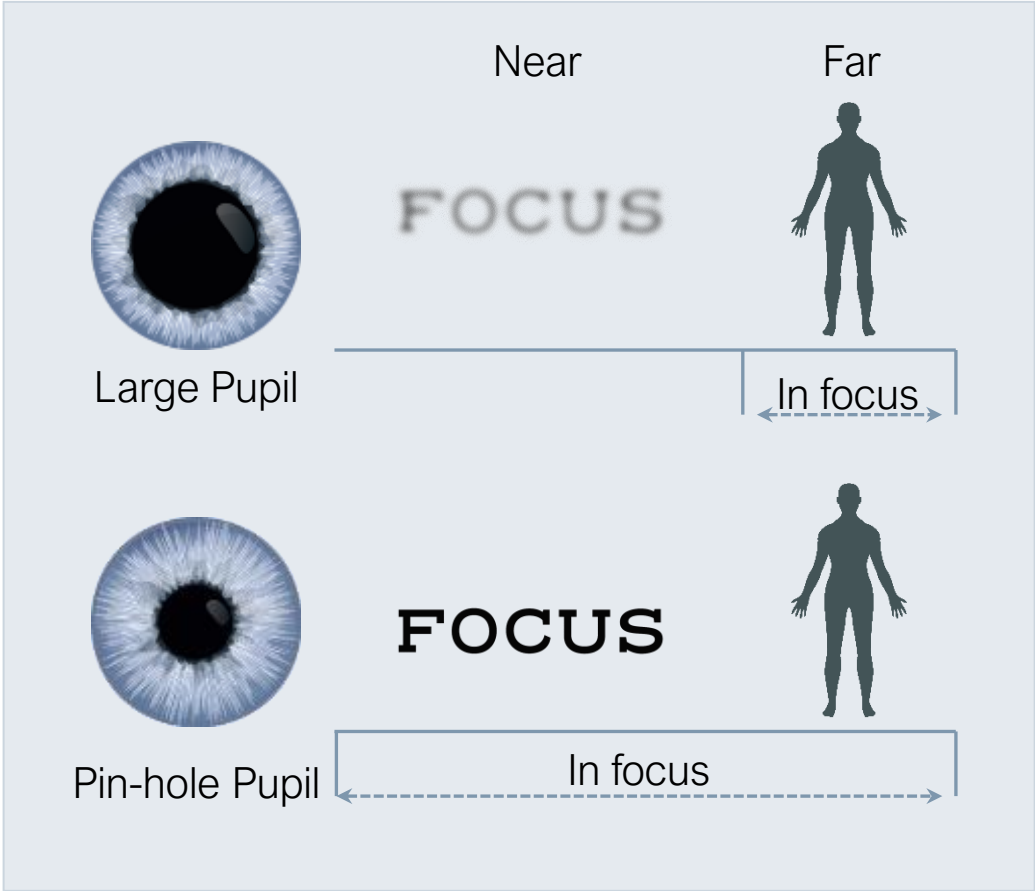
Presbyopia – Chronic Opportunity

Pupil Modulation Eye Drops May Replace Reading Glasses

Nyxol's Potential Differentiated Solution

- **"Pin-hole"** effect of Nyxol and low dose pilocarpine may improve near vision by increasing depth of focus as validated by other devices/therapies
- **More durable** combination of two miotics affecting different muscles (iris dilator and sphincter) involved in pupil size modulation
- **Tolerable** use with minimal side effects expected with chronic evening use of Nyxol

> *"This would just become part of my daily routine for my eyes to be able to see things up close. How convenient is that?"*
>
> *Presbyopic Patient, age 49*



Retinaeyedoctor.com, GlobalData Market Research Report, 2020

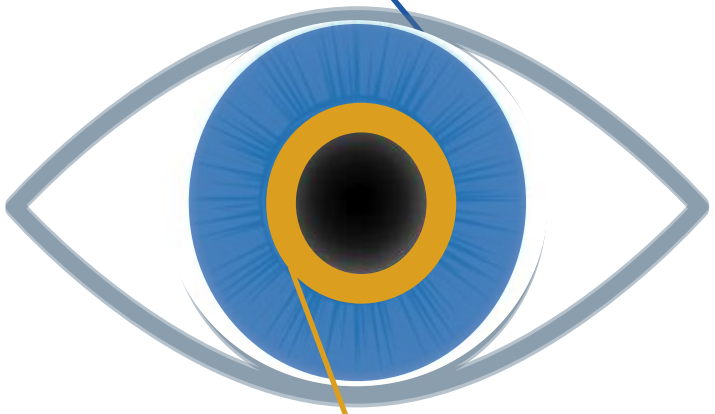
Synergistic Effects of Nyxol + Low-Dose Pilocarpine (LDP) Combo

Nyxol + LDP Demonstrated Efficacy and a Favorable Safety Profile in VEGA-1 Trial

0.75%Nyxol

Iris Dilator Muscle Inhibition

~0.7 to 1+ mm Reduction in PD[1]



Average PD in photopic conditions is 3.5 to 4.5 mm

0.4% LDP

~1 to 1.5+ mm Reduction in PD

Iris Sphincter Muscle Activation

1.5 to 2.5 mm PD reduction moves toward the pin-hole (1.6 to 2.5 mm, up to <3 mm)

≥ 3-line improvement in near vision expected

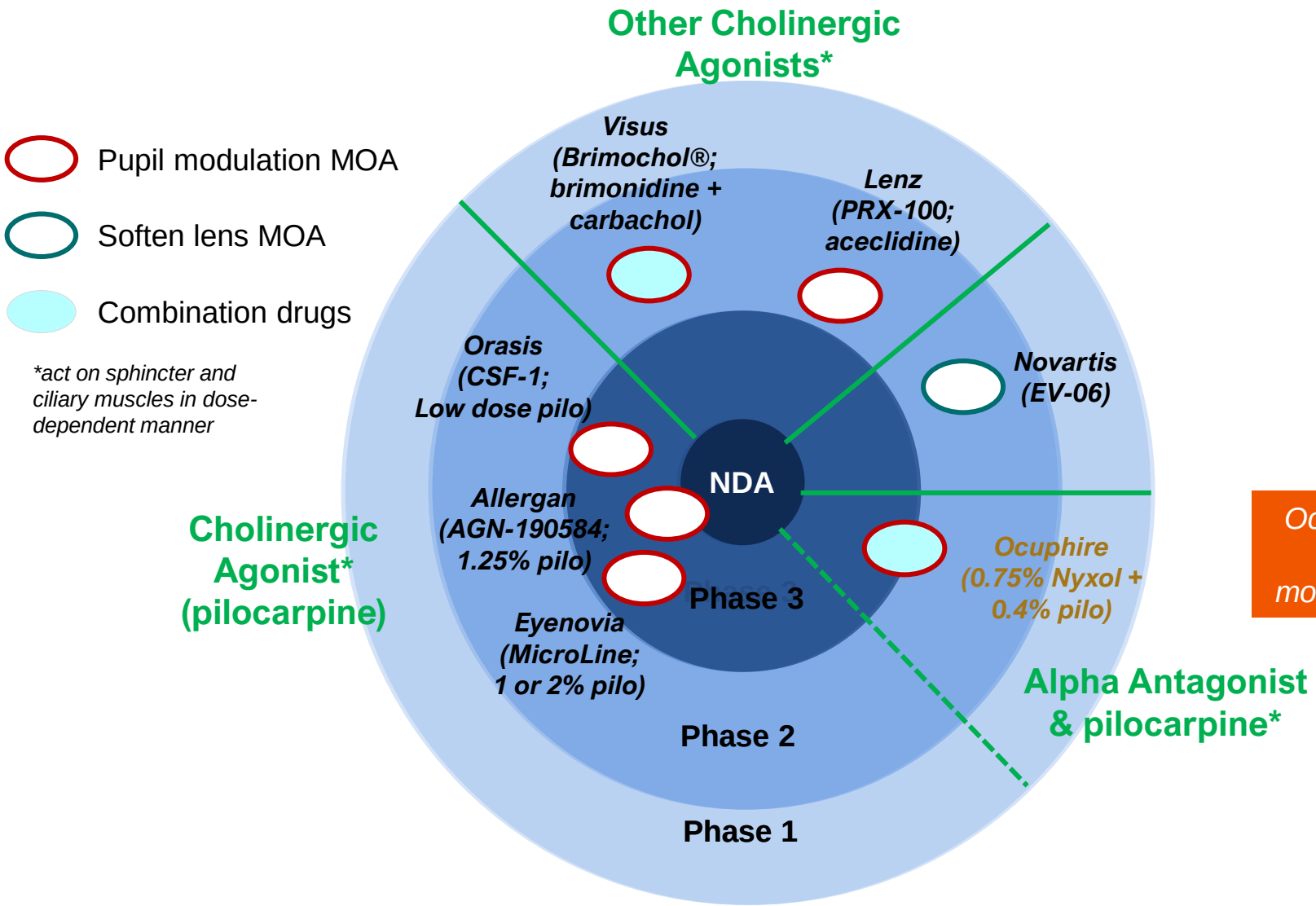
Benefits of Nyxol + LDP:

- **Observed longer durability of effect → inhibition of the dilator muscle with Nyxol may allow sphincter muscle to constrict without opposition and the long-acting effects of Nyxol**
- **Lower dose of pilocarpine showed a moderate miotic effect on sphincter muscle**
- **Lower dose of pilocarpine showed reduced known side effects such as headaches, browaches, and day/night distance loss**

Source: Ocuphire Clinical Trials

Presbyopia Eye Drops Competitive Landscape

Validation of Pupil Modulating Drops Achieving Pin-Hole Effect & Efficacy, Many with Pilocarpine



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

Corporate Websites, Grzybowski, A, Markeviciute A, Zemaitiene R. A Review of Pharmacological Presbyopia Treatment. 2020

Potential ‘Best in Class’ Presbyopia Drop

Competitive Approaches Limited by Safety/Tolerability, Durability, and Poor Distance Night Vision

Nyxol + LDP Presbyopia Treatment is Differentiated:

- ✓ **Statistically significant efficacy data**
- ✓ **Favorable safety profile**
- ✓ **Comfort and tolerability**
- ✓ **Fast onset**
- ✓ **Long duration**
- ✓ **Maintain good distance visual acuity (night/day)**
- ✓ **Novel tunable pupil modulation**

Future Milestones

2021 to 2022 Ocuphire Cadence of Milestones

Multiple Data Catalysts On Path To NDA(s)

2020

- ✓ Completion of APX3330 License
- ✓ ARVO 2020 Presentation for MIRA-1 & ORION-1
- ✓ FDA EOP2 Meeting May 2020
- ✓ Completion of Transaction (Nasdaq: OCUP) and concurrent $20M financing
- ✓ Initiate Phase 3 RM Trial
- ✓ Initiate Phase 3 NVD Trial
- ✓ Complete Nyxol Market Research
- ✓ Journal Publications

1H 2021

- ✓ Enrollment of Phase 3 RM Trial
- ✓ Initiate Phase 2 Presbyopia Trial
- ✓ **Report Positive Phase 3 Data for RM**
- ✓ Initiate Phase 2 DR/DME Trial
- ✓ Enrollment of Phase 2 Presbyopia Trial
- ✓ New Patent Claims
- ✓ Closed $15M registered direct offering
- ✓ **Report Positive Phase 2 Data for Presbyopia**

2H 2021

- ❑ ASCRS 2021 Presentation for MIRA-2 & VEGA-1
- ❑ **Initiate 2nd P3 RM and Pediatric RM trial for NDA**
- ❑ Enrollment of Phase 3 NVD Trial
- ❑ **Report Phase 3 Data for NVD**
- ❑ Enrollment of Phase 2 DR/DME Trial
- ❑ Industry Conferences & Publications
- ❑ Manufacture 3xRegistration Batches for Nyxol Blow-Fill-Seal (BFS) Eye Drops
- ❑ Complete 6-month Rabbit Tox Study

2022*

- ❑ **Report 2nd Ph3 RM Trial**
- ❑ **Report Pediatric RM trial**
- ❑ **Report Phase 2 Data for DR/DME**
- ❑ Initiate 2 Phase 3 Presbyopia Trials
- ❑ Initiate Chronic Ph3 Safety Trial (Nyxol /LDP)
- ❑ Complete 1 year CMC stability on 3xreg batches
- ❑ **Submit Nyxol NDA filing for RM in late 2022**
- ❑ Manufacture Commercial Batches of Nyxol Eye Drop

2023*

- ❑ Report Phase 3 Data for Presbyopia Trials
- ❑ Potential NDA for Nyxol in RM
- ❑ Potential Commercial Launch of Nyxol in US
- ❑ **Submit NDA filing for Nyxol for Presbyopia in 2023**

Ongoing partnering discussions with leading ophthalmic companies (including European and Asian players)

**Additional Studies for NVD and DR based on Data Readouts*

Ocuphire Pharma

Ocuphire PHARMA

Restore Vision & Clarity

Q&A

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