GEMINI 1 Phase 3: AGN-190584 Improves Intermediate Vision in Participants With Presbyopia

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Disclosures

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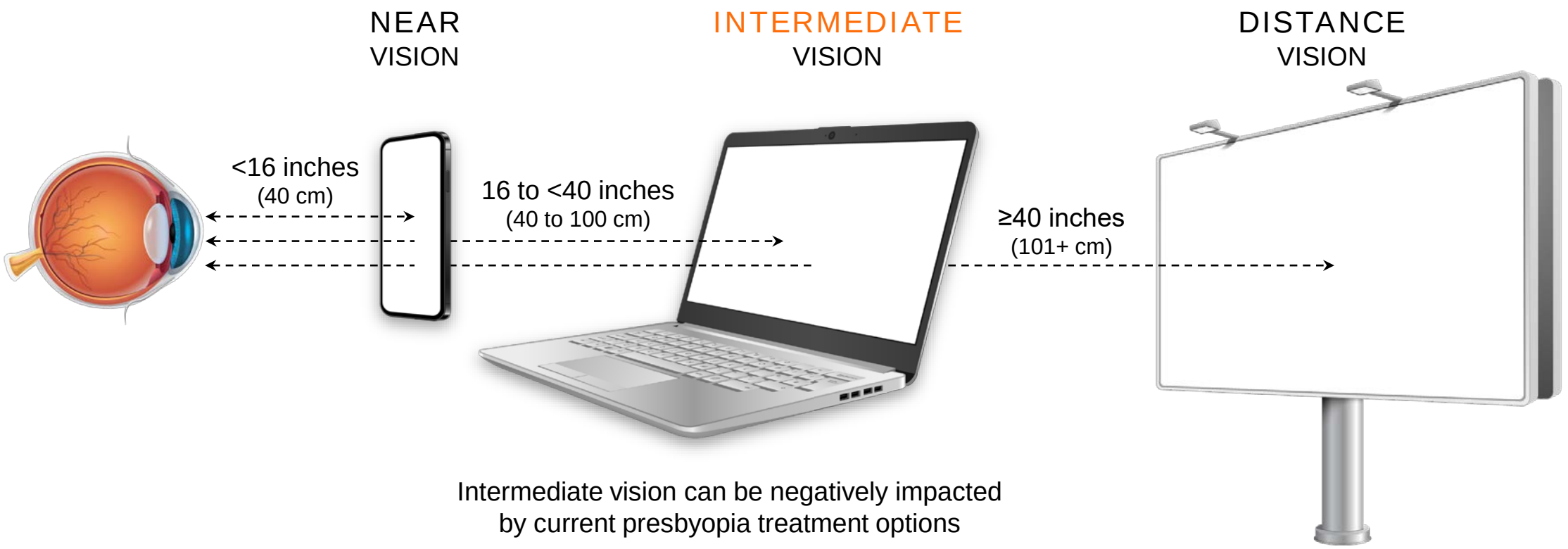
AGN-190584 is not an FDA approved drug

Presbyopia affects both near and intermediate vision



Intermediate vision can be negatively impacted by current presbyopia treatment options

Purpose: Evaluate the impact of AGN-190584 vs vehicle on INTERMEDIATE vision in GEMINI 1

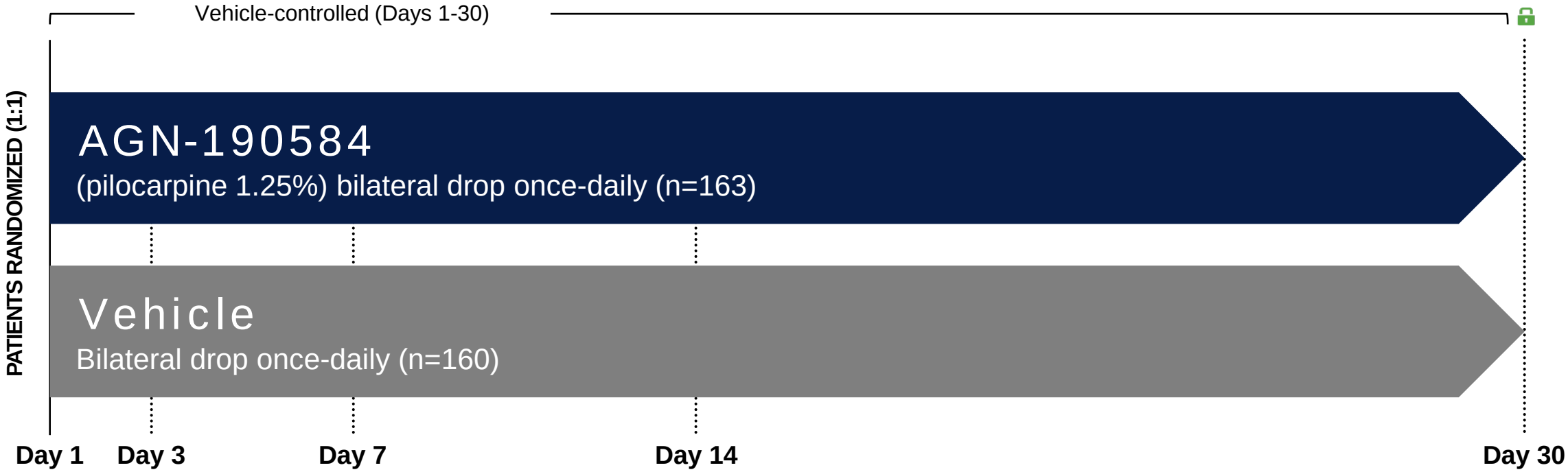
AGN-190584 is a once daily, topical, ophthalmic drop of optimized pilocarpine HCl 1.25% (in a proprietary vehicle) specifically designed to treat presbyopia

[1]AOA. https://www.aoa.org/AOA/Documents/CPG-17.pdf. Accessed June 18, 2021.

GEMINI 1

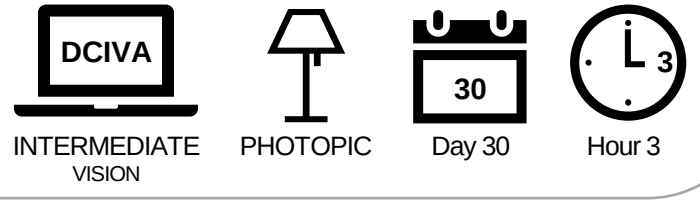
Study Design

Multicenter, double-masked, randomized, vehicle-controlled, phase 3 study



PRESPECIFIED SECONDARY ENDPOINT

Change from baseline in photopic DCIVA letters on Day 30, Hour 3
(assessed at 26 inches (66 cm) using LogMAR charts)



DCIVA = distance-corrected intermediate visual acuity

GEMINI 1

Key Inclusion/Exclusion Criteria

Key Inclusion Criteria

Aged 40-55

Mild to advanced presbyopes

Subjective complaints of poor near vision that impacts activities of daily living and the following objective measures at screening or baseline:

- Emmetropes or non-emmetropes with best distance correction sphere of -4.00 D to +1.00 D (inclusive) and cylinder ≤ ±2.00 D
- Mesopic, distance corrected near visual acuity (DCNVA) of 20/40 (J3+) to 20/100 (J10) in each eye

Key Ocular Exclusion Criteria

Severe dry eye

Corneal abnormalities potentially interfering with visual acuity

History of ocular surgery (except photorefractive keratectomy or LASIK)

Glaucoma or ocular hypertension

GEMINI 1

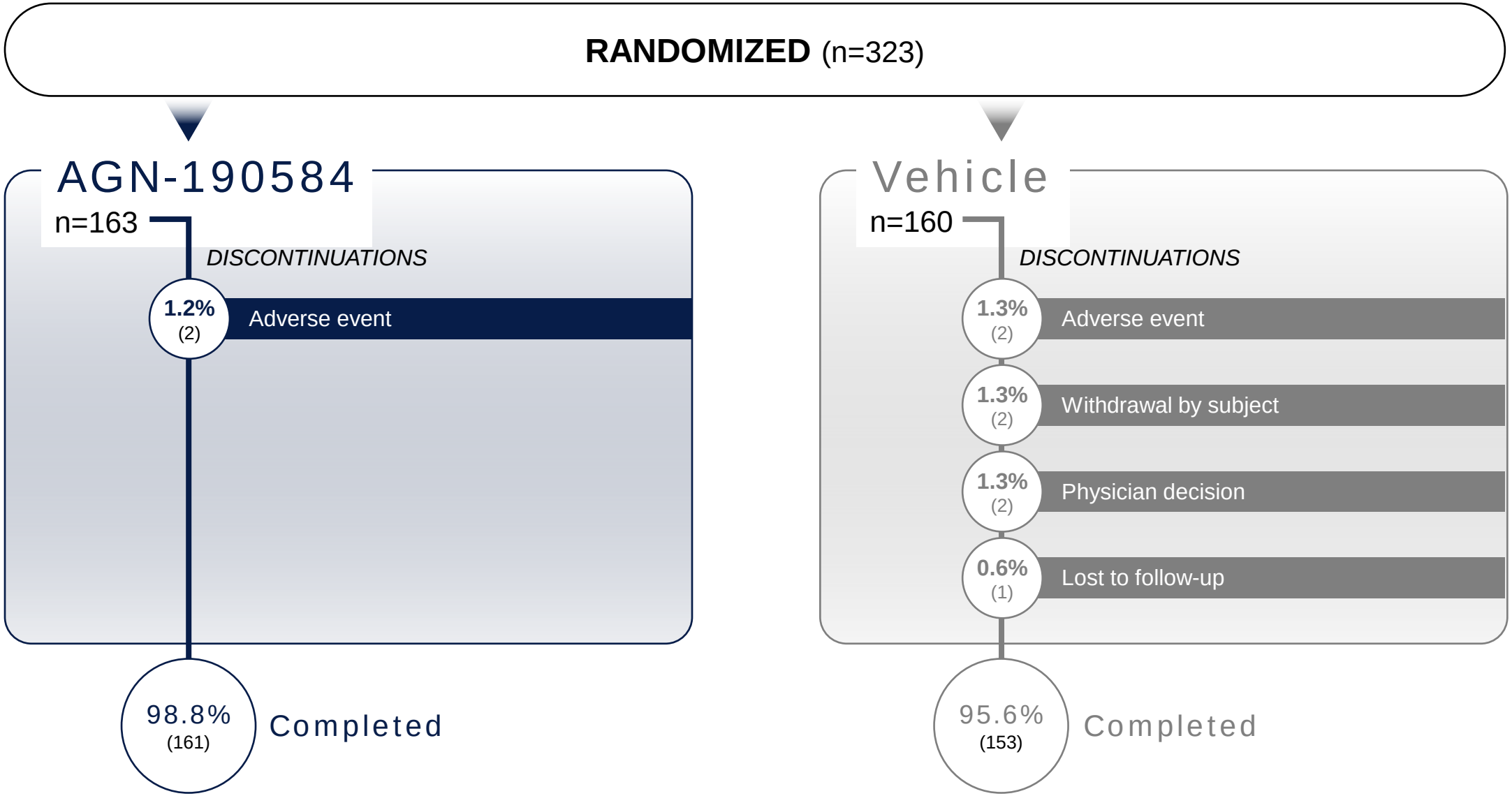
Baseline Demographics and Characteristics (ITT Population)

	AGN-190584 (N=163)	Vehicle (N=160)
Mean age, y (SD)	**49.5y** (3.8y)	**49.7y** (3.2y)
≤50 y, % (n)	**58.1%** (93)	**56.4%** (92)
>50 y, % (n)	**41.9%** (67)	**43.6%** (71)
Sex, % (n)		
Female	**69.3%** (113)	**76.3%** (122)
Race, % (n)		
White	**90.8%** (148)	**90.0%** (144)
Black/African American	**8.0%** (13)	**7.5%** (12)
Other	**1.2%** (2)	**2.5%** (4)
Mesopic, high-contrast, binocular DCNVA, % (n)		
20/40 to 20/63 (logMar)	**40.5%** (66)	**38.8%** (62)
Worse than 20/63 (logMar)	**59.5%** (97)	**61.3%** (98)
Iris color, % (n)		
Brown	**47.9%** (78)	**48.1%** (77)
Emmetrope, % (n)	**76.7%** (125)	**76.9%** (123)

ITT = intent to treat; DCNVA = distance-corrected near visual acuity

GEMINI 1

Discontinuations

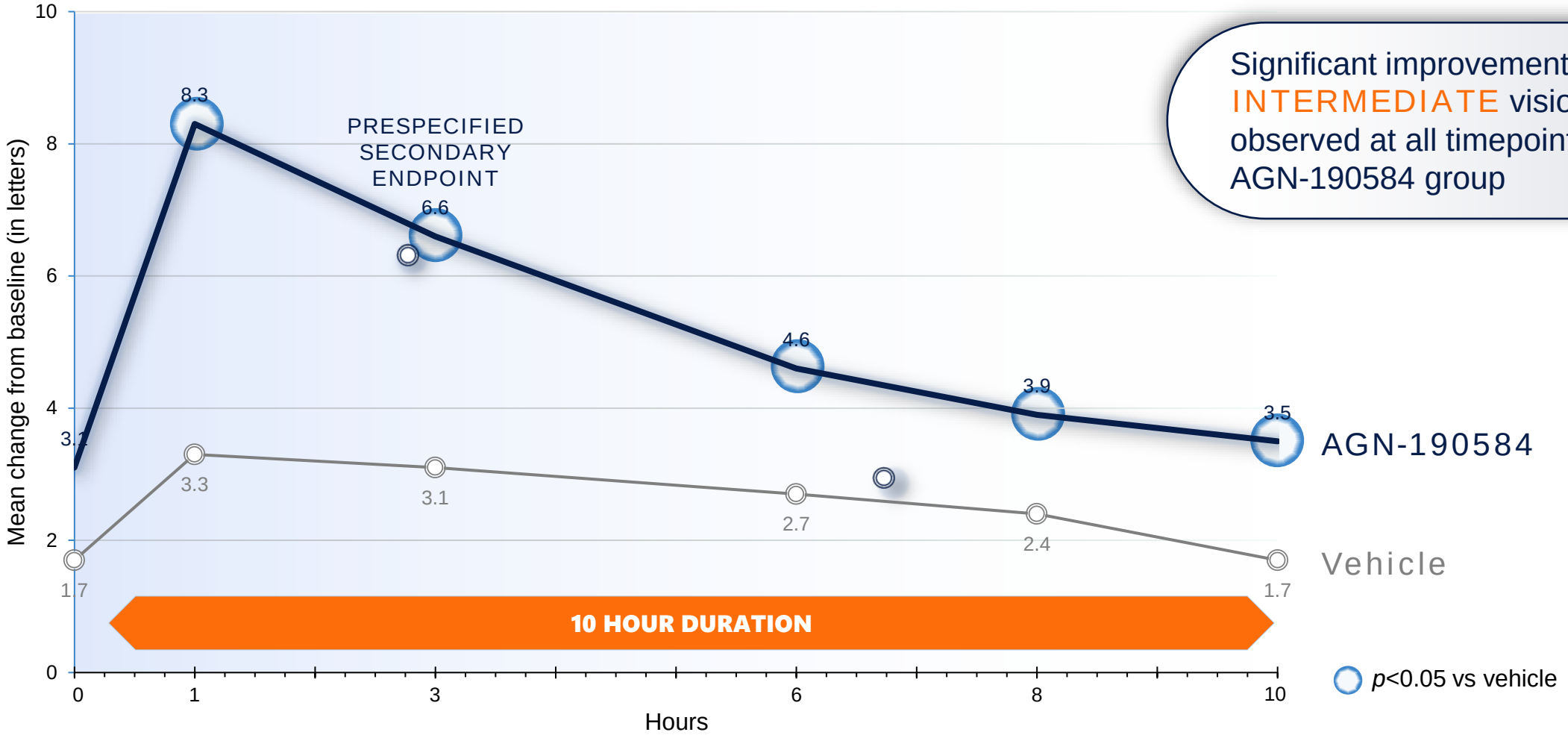


GEMINI 1

AGN-190584 Significantly Improves Intermediate Vision Compared to Vehicle

Change From Baseline in Photopic DCIVA at Day 30

DCIVA INTERMEDIATE VISION | PHOTOPIC | Day 30 | Hour 3



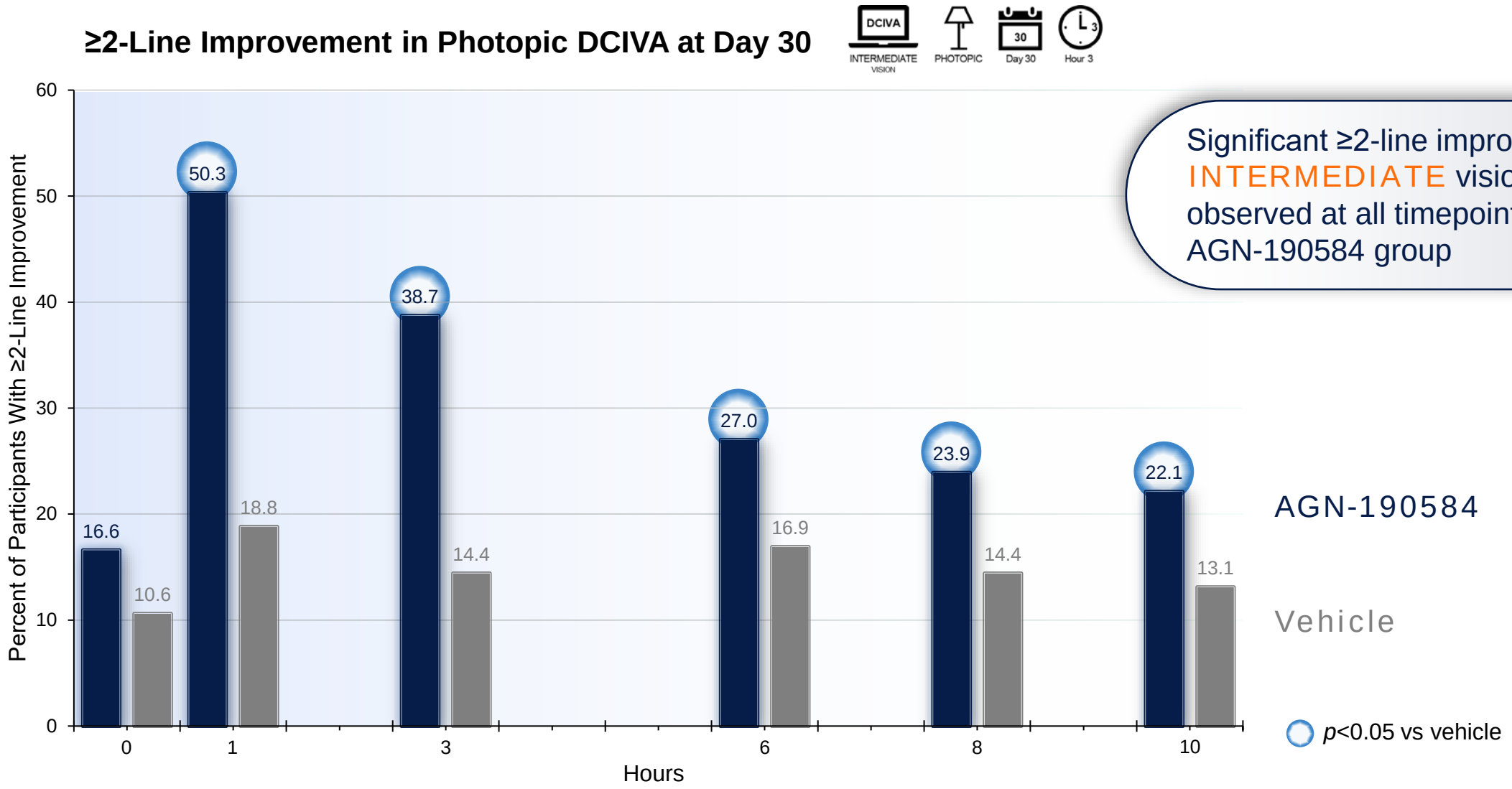
Significant improvement in INTERMEDIATE vision was observed at all timepoints in the AGN-190584 group

DCIVA = distance-corrected intermediate visual acuity

GEMINI 1

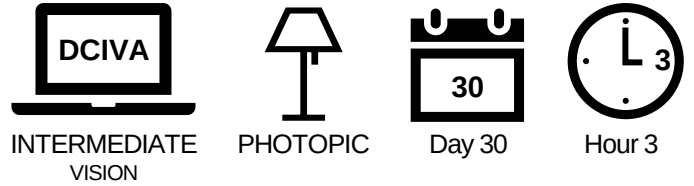
Significant ≥2-Line Improvement in Intermediate Vision With AGN-190584

≥2-Line Improvement in Photopic DCIVA at Day 30



DCIVA = distance-corrected intermediate visual acuity

Conclusions



GEMINI 1 met the prespecified secondary efficacy endpoint of DCIVA at day 30, hour 3

AGN-190584 was significantly better than vehicle for the improvement of intermediate vision for at least 10 hours

At all post-dose timepoints on day 30, significantly more participants achieved ≥2-line improvement in intermediate vision with AGN-190584 than vehicle

Thank you!