Evaluating Vision-related Reading Ability With a de Novo PRO Instrument in a Phase 3 Study of AGN-190584 (Pilocarpine 1.25%) for Presbyopia

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Patients are **FRUSTRATED** with presbyopia

90%

of participants in a survey of
1,339 presbyopes aged 40-55
years are frustrated or
irritated with presbyopia[1]
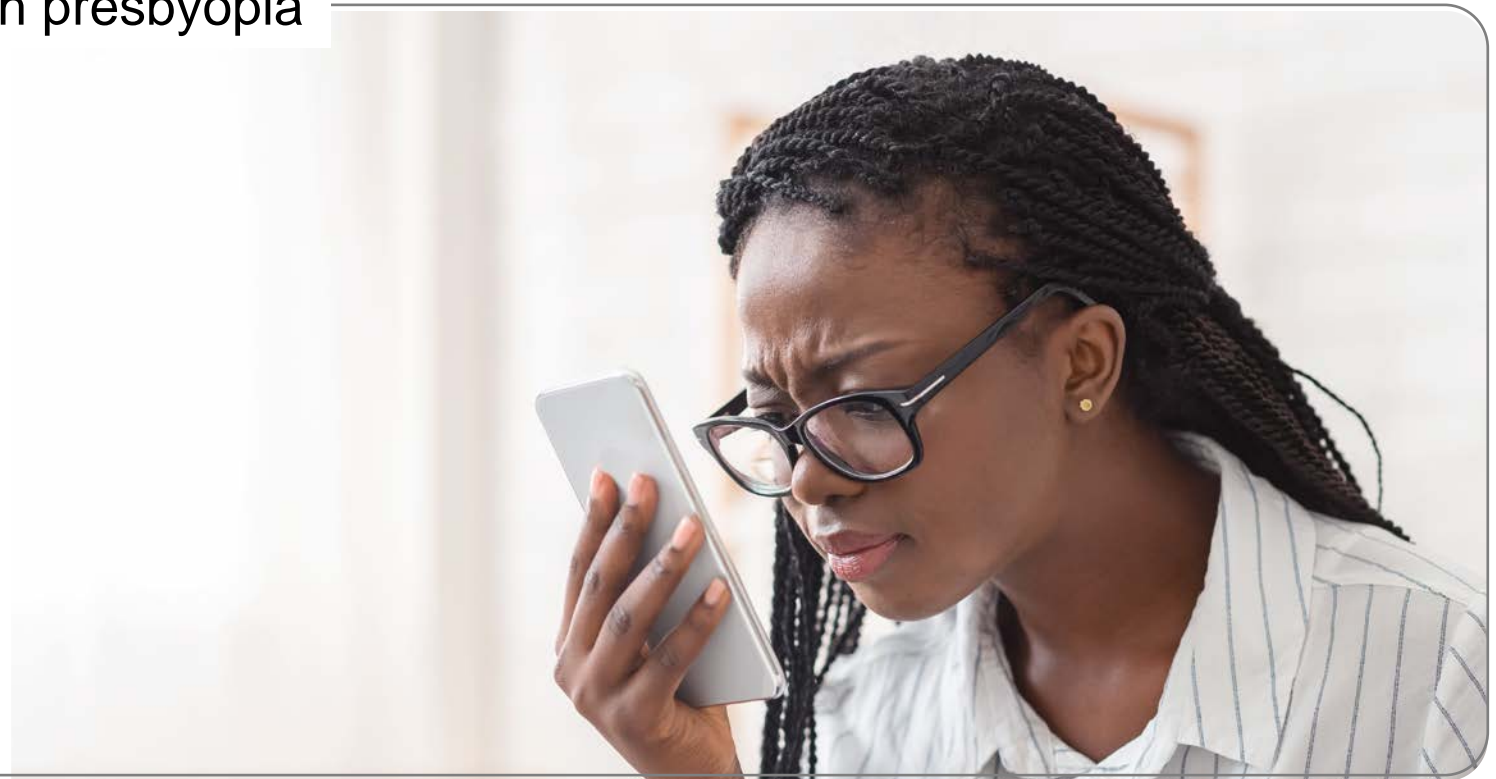
Purpose: Evaluate the impact of AGN-190584 vs vehicle on **PROs (near vision reading performance and satisfaction)** in GEMINI 1

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

PRO = patient reported outcome
[1]Data on file, Allergan; Full Quantitative Summary.

The Validated NVPTQ Evaluates 4 Reading Tasks[1]

BOOK **NEWSPAPER** **MENU** **NUTRITION LABEL**

NVPTQ Items*

Performance Score	0	1	2	3	4	5
	← Rating of ability to read each item →					
	Could Not Read	Poor	Fair	Good	Very Good	Excellent

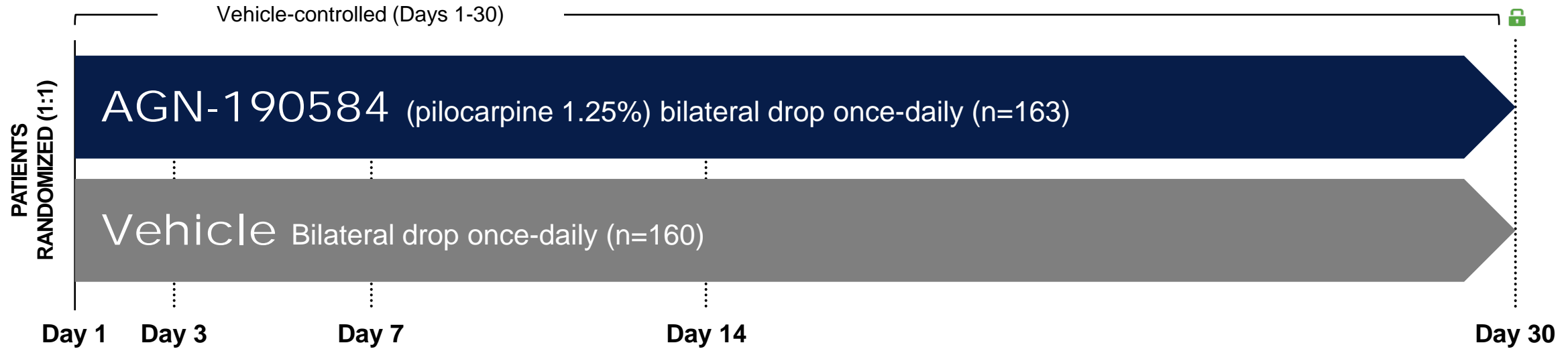| Satisfaction Score	0	1	2	3	4
	← Satisfaction with ability to read each item →				
	Very Dissatisfied	Dissatisfied	Neither	Satisfied	Very Satisfied

NVPTQ = Near Vision Presbyopia Task-based Questionnaire

*NVPTQ also asks 1 question for each reading task on whether the presbyope had to squint while reading text.

[1]Shirneshan E, et al. Psychometric evaluation of the Near Vison Presbyopia Task-Based Questionnaire using phase 2b clinical trial data. Presented at the American Academy of Optometry Annual Meeting, October 7–22, 2020.
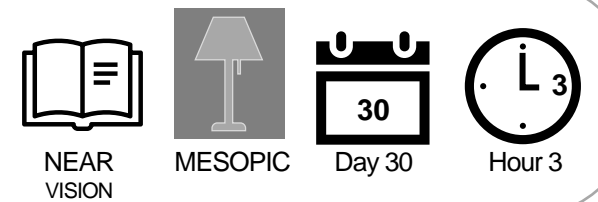
GEMINI 1
Study Design

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

Vehicle-controlled (Days 1-30)

AGN-190584 (pilocarpine 1.25%) bilateral drop once-daily (n=163)

Vehicle Bilateral drop once-daily (n=160)

PATIENTS RANDOMIZED (1:1)

Day 1   Day 3   Day 7   Day 14   Day 30

PRESPECIFIED SECONDARY ENDPOINTS
Mean change from baseline in mesopic **NVPTQ performance** and **satisfaction** on Day 30, Hour 3

NEAR VISION   MESOPIC   Day 30   Hour 3

ADDITIONAL PRESPECIFIED ENDPOINTS

Mean change from baseline in photopic NVPTQ performance and satisfaction on Day 30, Hour 3
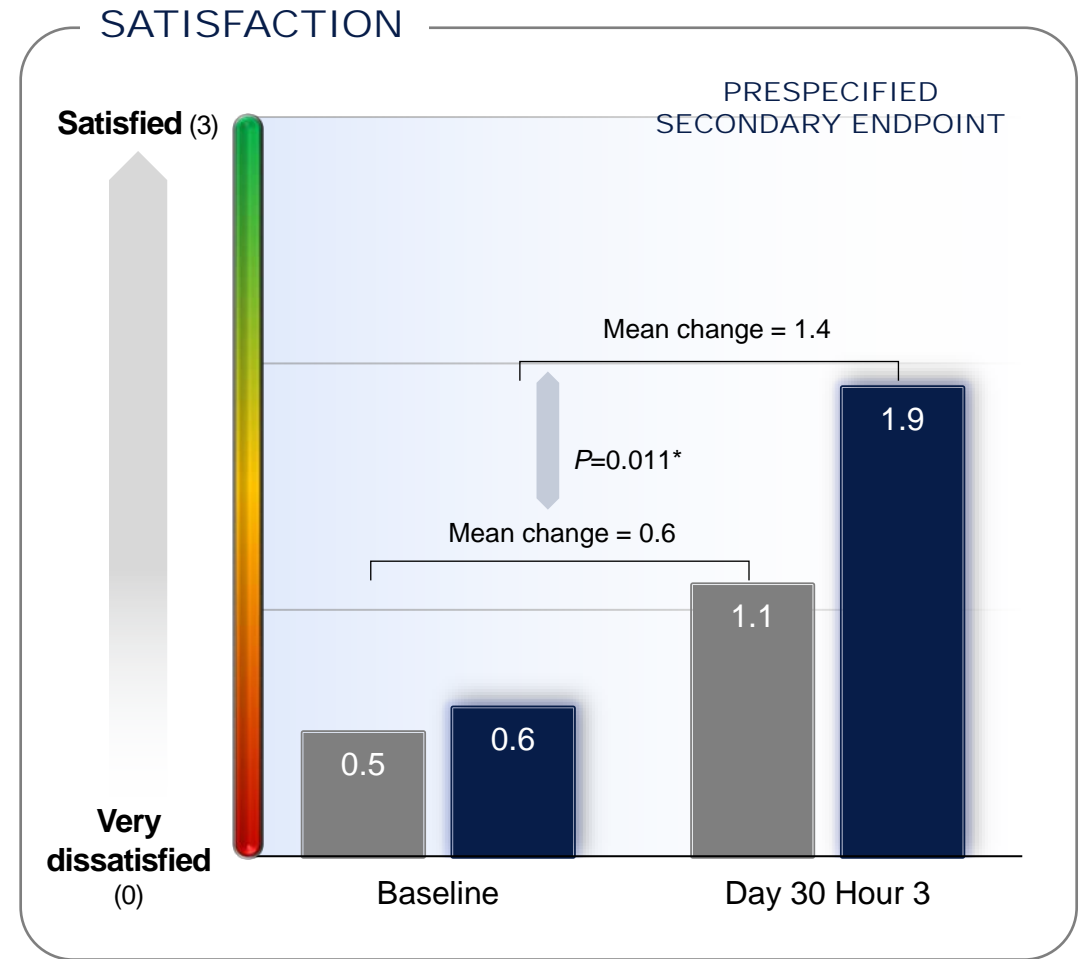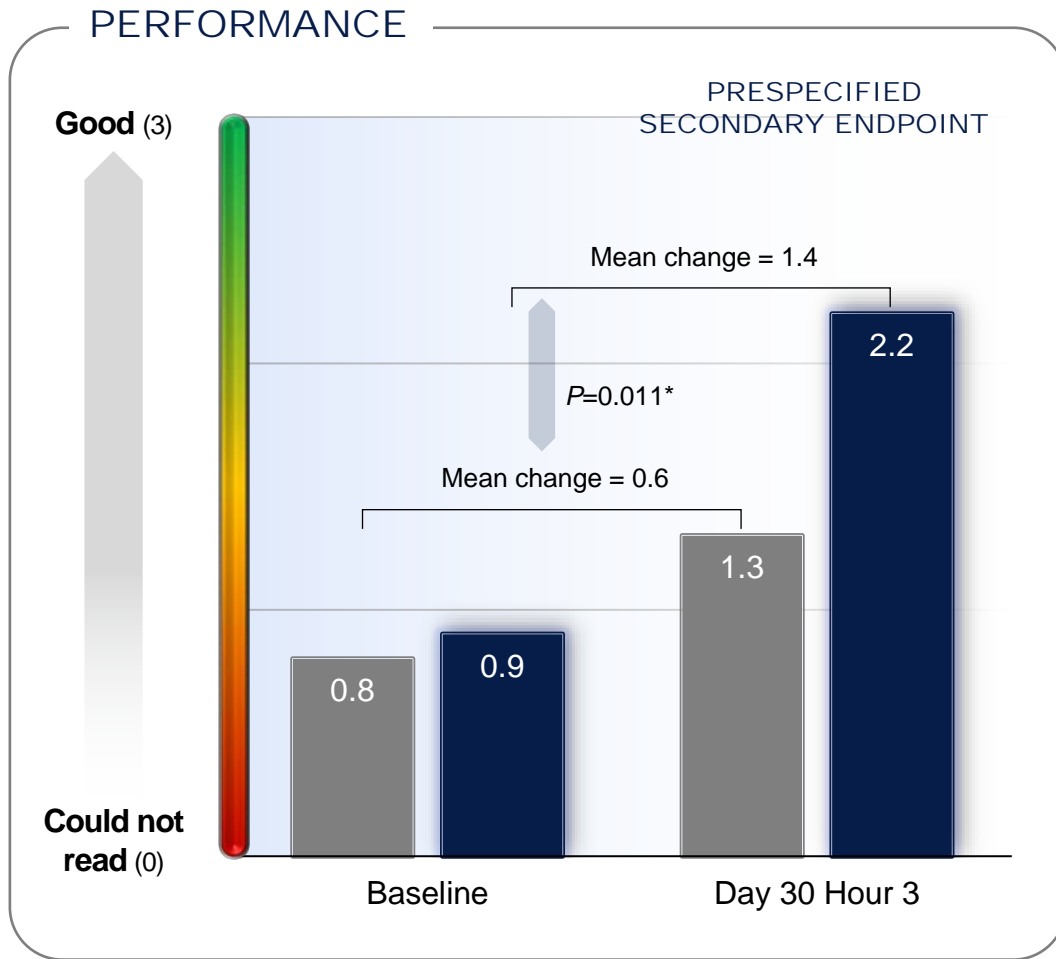
NEAR VISION   PHOTOPIC   Day 30   Hour 3
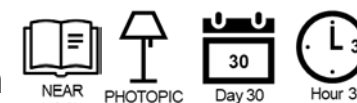
Mesopic NVPTQ performance and satisfaction responders on Day 30, Hour 3

NEAR VISION   MESOPIC   Day 30   Hour 3

GEMINI 1

AGN-190584 Significantly Improves Mesopic NVPTQ Performance and Satisfaction

Change from Baseline in Mesopic NVPTQ

NEAR VISION MESOPIC Day 30 Hour 3

PERFORMANCE

PRESPECIFIED SECONDARY ENDPOINT

Good (3)

Mean change = 1.4

2.2

P=0.011*

Mean change = 0.6

1.3

0.8   0.9

Could not read (0)

Baseline   Day 30 Hour 3

SATISFACTION

PRESPECIFIED SECONDARY ENDPOINT

Satisfied (3)

Mean change = 1.4

1.9

P=0.011*

Mean change = 0.6

1.1

0.5   0.6

Very dissatisfied (0)

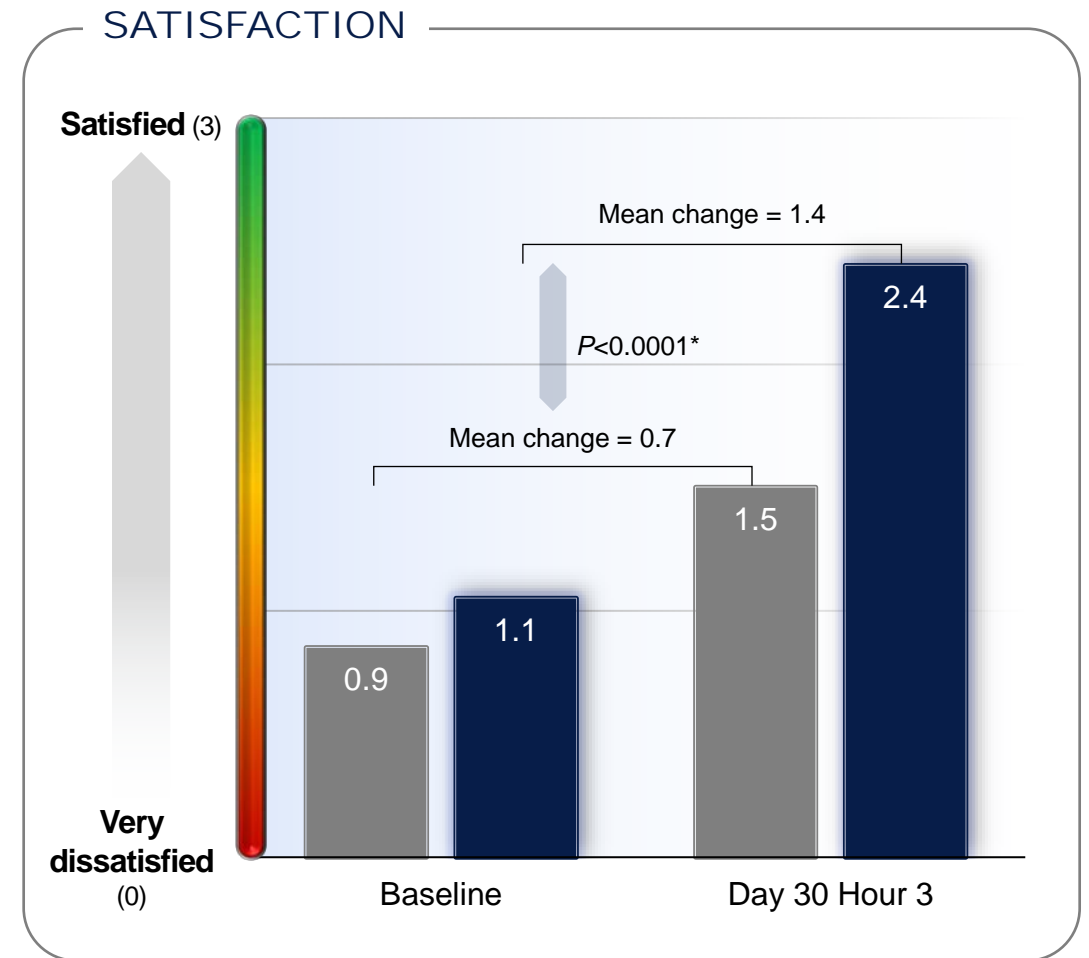Baseline   Day 30 Hour 3

■ **AGN-190584** ■ **Vehicle**

NVPTQ = Near Vision Presbyopia Task-based Questionnaire
*Score difference between groups baseline vs Day 30, Hour 3 was 0.8 points for both NVPTQ performance and satisfaction.

GEMINI 1

AGN-190584 Significantly Improves Photopic NVPTQ Performance and Satisfaction

Change from Baseline in Photopic NVPTQ

NEAR VISION PHOTOPIC Day 30 Hour 3

PERFORMANCE

Good (3)

Mean change = 1.5

2.9

P<0.0001*

Mean change = 0.6

1.9

1.3   1.4

Could not read (0)

Baseline   Day 30 Hour 3

SATISFACTION

Satisfied (3)

Mean change = 1.4

2.4

P<0.0001*

Mean change = 0.7

1.5

0.9   1.1

Very dissatisfied (0)

Baseline   Day 30 Hour 3

■ **AGN-190584**   ■ **Vehicle**
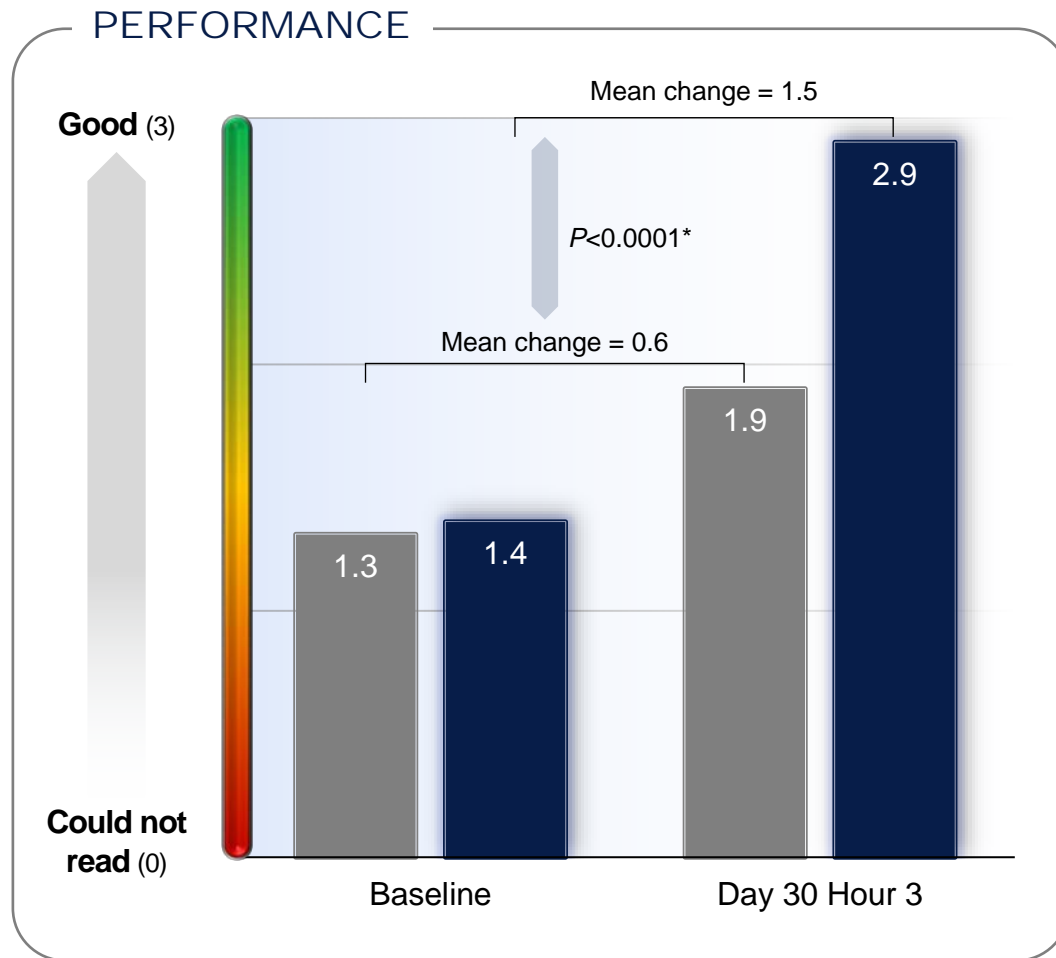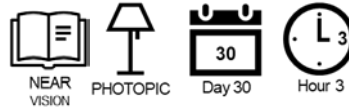
NVPTQ = Near Vision Presbyopia Task-based Questionnaire
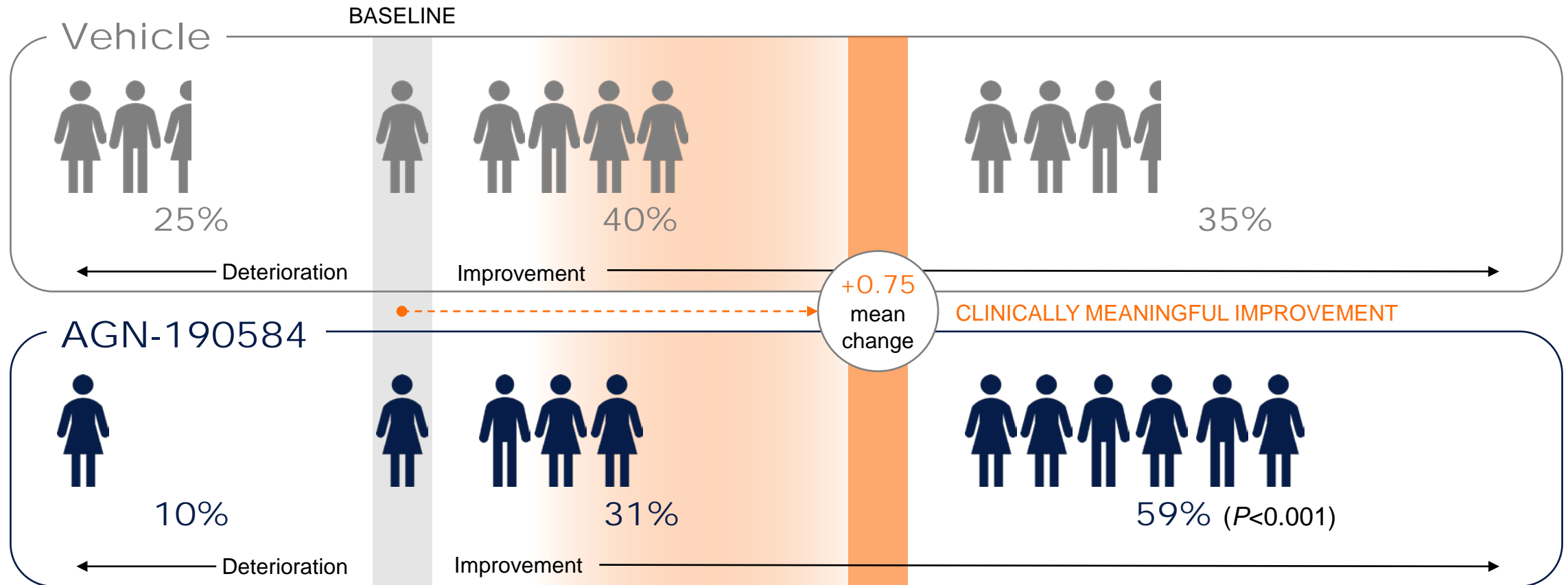*Score difference between groups baseline vs Day 30, hour 3) was 0.9 points for NVPTQ performance and 0.7 for NVTPQ satisfaction

Consistently More NVPTQ Performance Responders with AGN-190584

Mesopic NVPTQ Performance Responders*

NEAR VISION | MESOPIC | Day 30 | Hour 3

Vehicle

BASELINE

25%

40%

35%

Deterioration ← | → Improvement

+0.75 mean change

AGN-190584

CLINICALLY MEANINGFUL IMPROVEMENT

10%

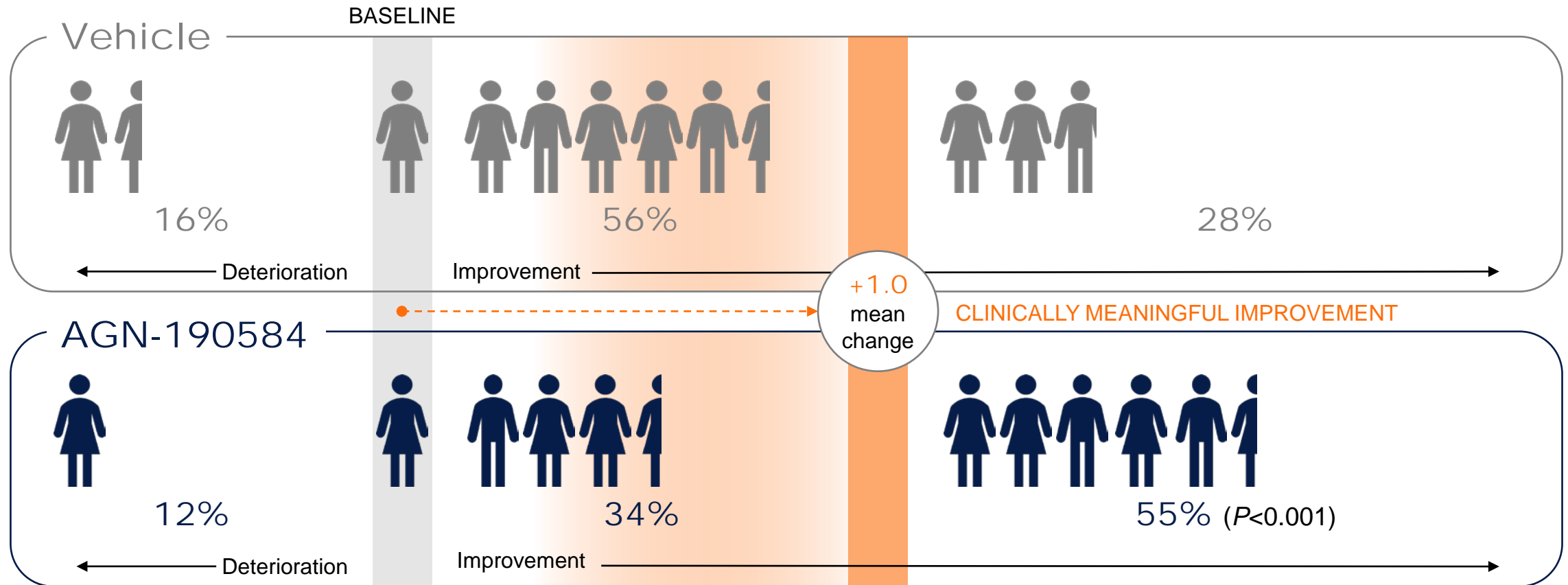**31%**

59% (*P*<0.001)

Deterioration ← | → Improvement

NVPTQ = Near Vision Presbyopia Task-based Questionnaire
*NVPTQ performance responders = mean change from baseline of ≥0.75.

GEMINI 1
Consistently More NVPTQ Satisfaction Responders with AGN-190584

Mesopic NVPTQ Satisfaction Responders*

NEAR VISION   MESOPIC   Day 30   Hour 3

BASELINE

Vehicle

16%   56%   28%

Deterioration   Improvement

+1.0 mean change

CLINICALLY MEANINGFUL IMPROVEMENT

AGN-190584

12%   34%   55% (*P*<0.001)

Deterioration   Improvement

NVPTQ = Near Vision Presbyopia Task-based Questionnaire
*NVPTQ satisfaction responders = mean change from baseline of ≥1.0.

NEAR VISION PHOTOPIC MESOPIC Day 30 Hour 3
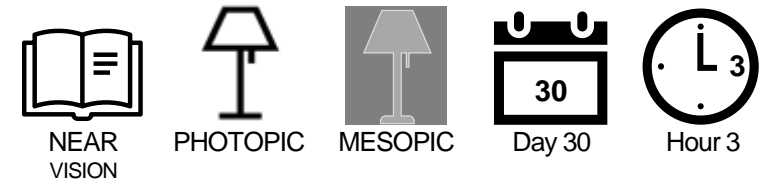
GEMINI 1 met the prespecified secondary efficacy endpoints related to NVPTQ at day 30, hour 3 (significant improvement in mesopic NVPTQ performance and satisfaction with AGN-190584)

Significant improvement was also seen in photopic NVPTQ performance and satisfaction with AGN-190584 vs vehicle

Consistently more presbyopes were responders to both NVPTQ performance and satisfaction with AGN-190584 vs vehicle

Thank you!