

Assessing Presbyopia Impacts and Coping Behaviors with De Novo PRO Instruments in a Phase 3 Study of AGN-190584 (Pilocarpine 1.25%)

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Elaheh Shirneshan, Sungwook Lee, and Joanna Campbell are employees of AbbVie Inc and may hold AbbVie stock.

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The eye drop formulations used in this study are investigational.

The BURDEN of Presbyopia^{1,2}



Purpose: Evaluate the impact of AGN-190584 (pilocarpine HCl 1.25%) vs vehicle using PROs (impacts on daily life and use of compensatory coping behaviors, and treatment satisfaction) in GEMINI 1

PRO = patient reported outcome

¹Labiris G, et al. *Eye Vis.* 2017;4:2:doi:10.1186/s40662-016-0067-1. ²Goertz AD, et al. *Acta Ophthalmol.* 2014;92:497-500.

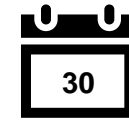
PICQ and PPSQ Analyses

Presbyopia Impact and Coping Questionnaire (PICQ)

- Administered at baseline (Day 1) and on Day 30 Hour 3

PRESPECIFIED SECONDARY ENDPOINTS

Mean change from baseline in **PICQ Impact and Coping** summary scores on Day 30, Hour 3



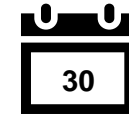
Day 30



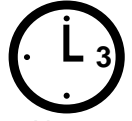
Hour 3

ADDITIONAL ASSESSMENTS

Proportion of PICQ responders to AGN-190584 with a **clinically meaningful change** (≥ 1 -point improvement)* in Coping and Impact scores on Day 30, Hour 3



Day 30



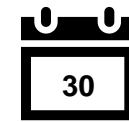
Hour 3

Presbyopia Patient Satisfaction Questionnaire (PPSQ)

- Administered on Day 30, Hour 3

ADDITIONAL ASSESSMENTS

Between-group comparison of the overall **PPSQ Satisfaction** Score on Day 30, Hour 3



Day 30









Hour 3

*Individual-level meaningful change threshold as proposed by gold standard psychometric analysis.







The Validated PICQ Evaluates the Impacts of Presbyopia and Coping Strategies

IMPACT OF PRESBYOPIA OVER THE PAST 7 DAYS

					
Rely on others	Rest eyes	Feel older	Feel self-conscious	Take longer to complete a task	Inconvenient

← Rating of each item (Score range: 0 = Never; 4 = All of the Time) →

COPING STRATEGIES FOR PRESBYOPIA OVER THE PAST 7 DAYS

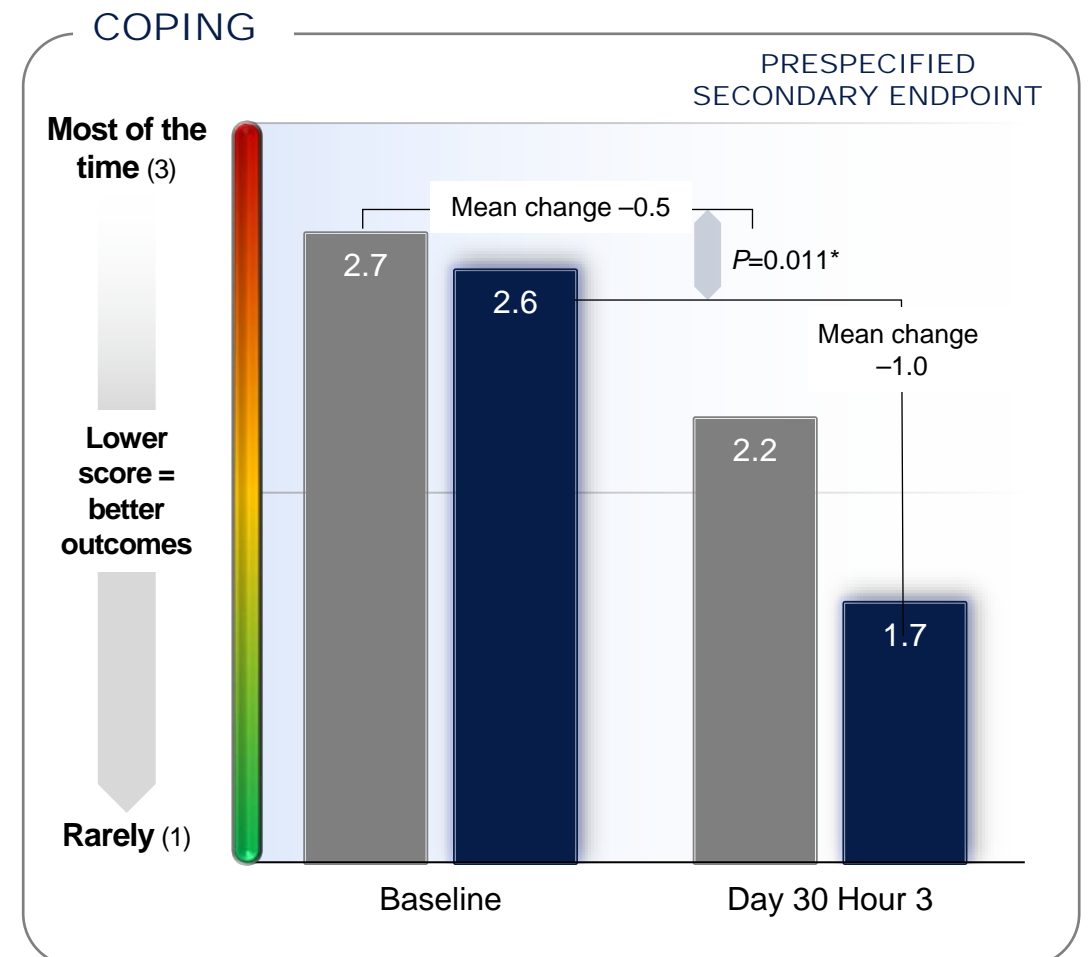
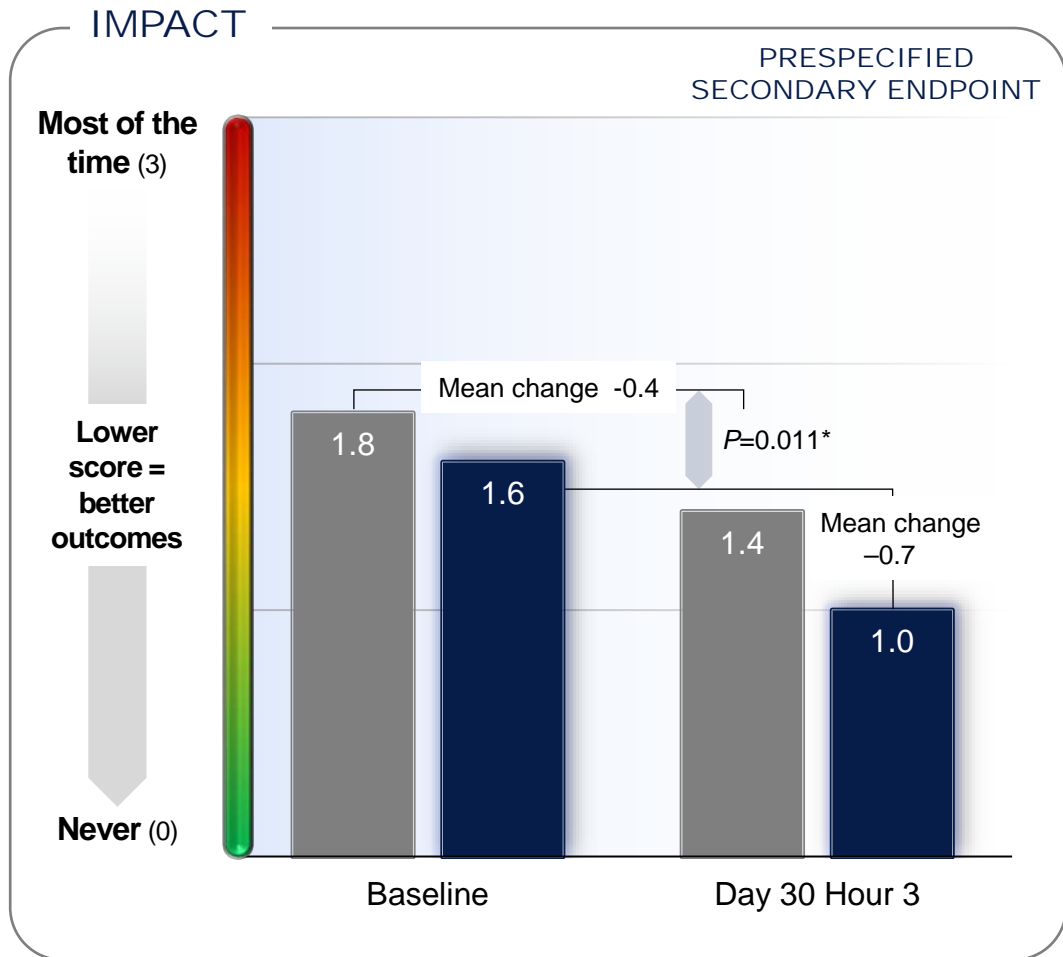
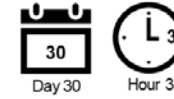
Aa	Aa						
Normal sized text	Small sized text	Information on a computer	Information on a cell phone	Increase font size	Use glasses to read close	Hold reading materials farther out or closer	Squint to read

← Rating of each item (Score range: 0 = Never; 4 = All of the Time) →

GEMINI 1

AGN-190584 Significantly Reduces Impact and Coping Behaviors

Mean Change from Baseline in PICQ Impact and Coping Summary Scores



PICQ = Presbyopia Impact and Coping Questionnaire

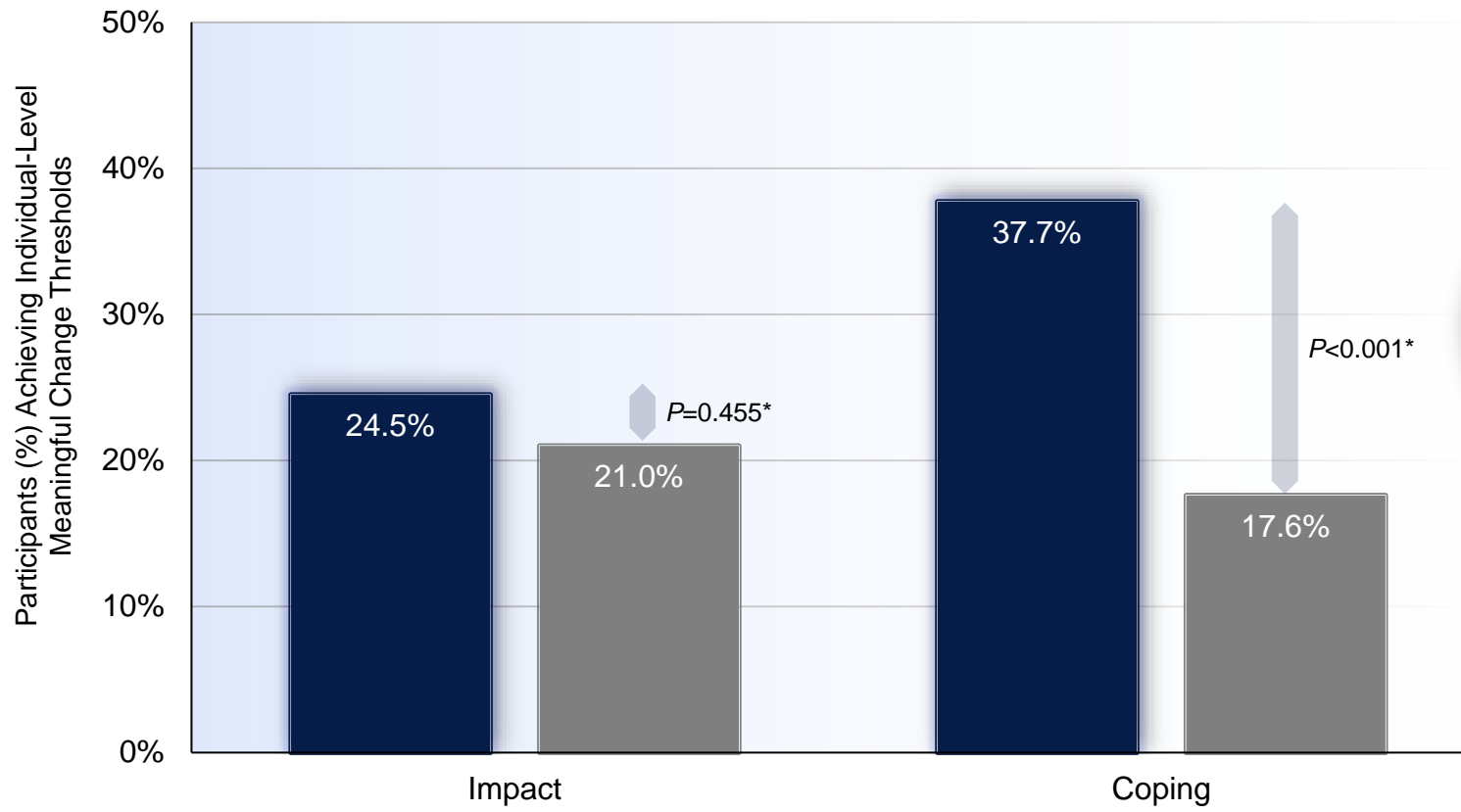
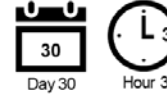
*Score difference between groups baseline vs Day 30, Hour 3 was -0.3 points for PICQ impact and -0.5 for PICQ coping

■ Vehicle ■ AGN-190584

GEMINI 1

Proportion of Participants Achieving Individual-Level Clinically Meaningful Improvement in Presbyopia Impact and Coping Scores

PICQ Impact and Coping Summary Score Responders*










Significantly more AGN-190584 participants reported a **CLINICALLY MEANINGFUL REDUCTION** in coping behaviors

PICQ = Presbyopia Impact and Coping Questionnaire
 *P<0.001 for Coping and **P=0.455 for Impact, AGN versus vehicle. Intent-to-treat population.
 -1.0 point is the proposed individual-level meaningful change threshold for PICQ Coping and Impact scores

The Validated PPSQ Evaluates Treatment Satisfaction

TREATMENT SATISFACTION

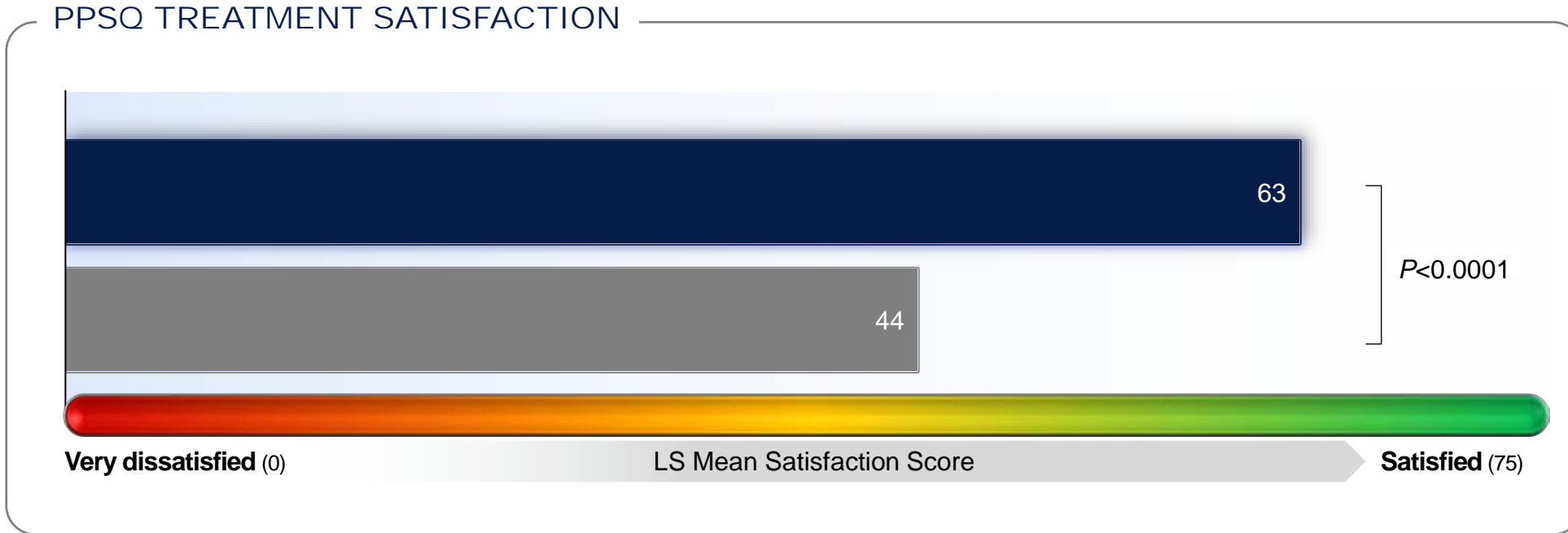
						
Effect on vision	Satisfaction with ability to perform daily activities	Satisfaction with unassisted near vision	Satisfaction with unassisted near vision in dim light	Satisfaction with ease of use	Met expectations	Likelihood to use over previous form of vision correction
Rating (Score range: 0 = Far Worse; 7= Complete Improvement)	Rating of each item (Score range: 0 = Very Dissatisfied/Far Worse than Expected/Extremely Unlikely; 4 = Very Satisfied/Far Better than Expected/Extremely Likely)					

All items are transformed and range in score from 0 to 100, with higher scores indicating higher levels of patient satisfaction

GEMINI 1

Participants are More Satisfied With AGN-190584 vs Vehicle

PPSQ Treatment Satisfaction Score at Day 30, Hour 3



PPSQ PRO Endpoint was met, participants were significantly **MORE SATISFIED** with aspects of study medication compared with vehicle

LS Mean = least squares mean



In GEMINI 1, the validated PICQ and PPSQ demonstrated significant patient reported outcome benefits with AGN-190584 vs vehicle in presbyopia



Participants who received AGN-190584 had statistically significant and clinically meaningful greater reduction in the use of presbyopia-related coping behaviors such as squinting or changing the font size on electronic screens, compared with those who received vehicle



Participants who received AGN-190584 reported greater satisfaction with different aspects of the study medication compared with participants receiving vehicle

Thank you!