# Impact of Baseline Imbalances on the Efficacy of Pegcetacoplan for the Treatment of Geographic Atrophy (GA): A Post-hoc Analysis of OAKS, DERBY, and FILLY

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# Disclosures

- Sunir Garg has the following financial interests or relationships to disclose:
  - Consultant: Allergan, Apellis, Bausch and Lomb, Boehringer Ingelheim, Coherus, Genentech, Merck Manual
  - Grants: American Academy of Ophthalmology, Apellis, Boehringer Ingelheim, Genentech, Regeneron
- Study funded by Apellis Pharmaceuticals

# Introduction

- Geographic atrophy is a heterogeneous disease[1] and the OAKS and DERBY trials enrolled broad patient populations
- Goal of randomization is to balance risk factors between treatment groups. However, chance imbalance can still occur
- Chance imbalance of risk factors may introduce biases to the estimate of treatment effect. Such biases may potentially be corrected through covariate adjustment

- **Objective:** To examine the potential impact of baseline imbalances on the GA lesion growth rate of OAKS, DERBY, and FILLY
- This covariate adjustment is a post-hoc analysis of the OAKS (NCT03525613), DERBY (NCT03525600), and FILLY (NCT02503332) studies, providing supportive evidence for the primary analysis. It is not intended or qualified to replace the primary analysis

GA=geographic atrophy.

1. Scholl HPN et al. *Ophthalmic Res* 2021;64:888–902.

# Global Phase 3 program: Design of studies (OAKS and DERBY)

OAKS DERBY

**Patients with GA secondary to AMD**
**~600 patients at ~200 sites globally in 2 studies (1258 enrollees total)**

APL-2 303 (DERBY)
CT.gov identifier:
NCT03525600

APL-2 304 (OAKS)
CT.gov identifier:
NCT03525613

**Double-masked**

**Randomized 2:2:1:1**

| Pegcetacoplan 15 mg/0.1 mL monthly | Pegcetacoplan 15 mg/0.1 mL EOM | Sham monthly | Sham EOM |
|---|---|---|---|

**Analysis Month 18**

**Primary endpoint at 12 months**
**Change in total area of GA lesions based on fundus autofluorescence**

**End of study at 24 months**

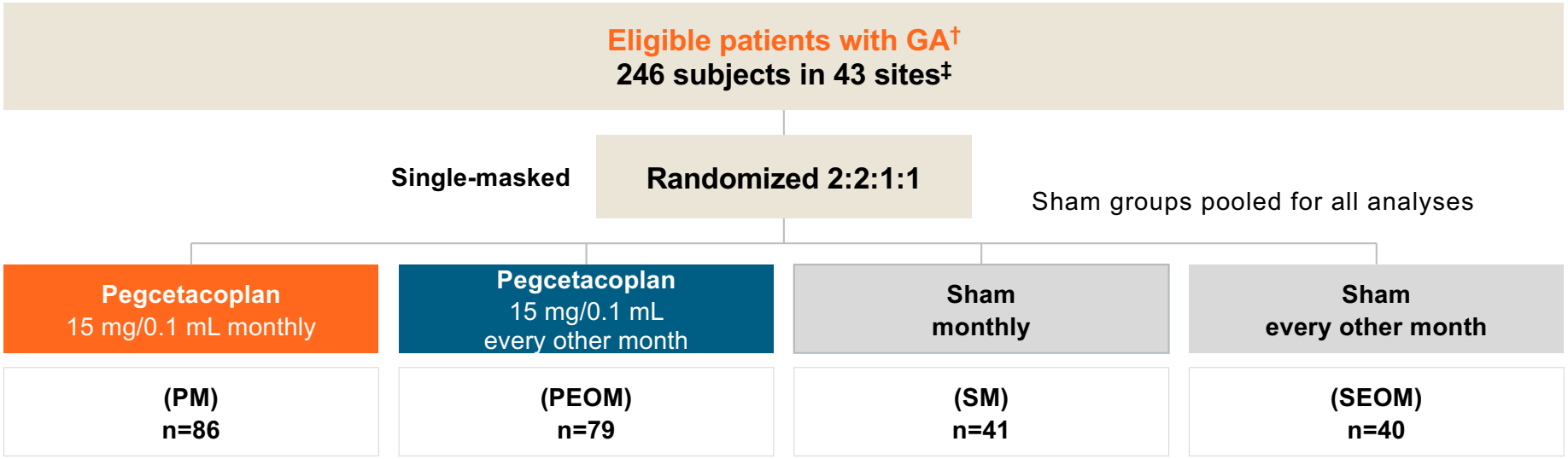
- BCVA, LL-BCVA, low-luminance deficit
- Reading speed
- NEI VFQ-25
- FRI Index composite score
- Microperimetry (OAKS only) – MAIA device

**GALE open-label extension study (3 years)**

APL-2 305 (GALE)
CT.gov identifier:
NCT04770545

AMD=age-related macular degeneration; BCVA=best corrected visual acuity; EOM=every other month; FRI=functional reading independence; GA=geographic atrophy; LL=low luminance; MAIA=Macular Integrity Assessment; NEI-VFQ=National Eye Institute Visual Function Questionnaire-25.

# FILLY: Phase 2 randomized controlled trial: Study arms and endpoints




## Primary efficacy endpoint

Change in square root of the GA lesion size from baseline to Month 12

## Primary safety endpoint

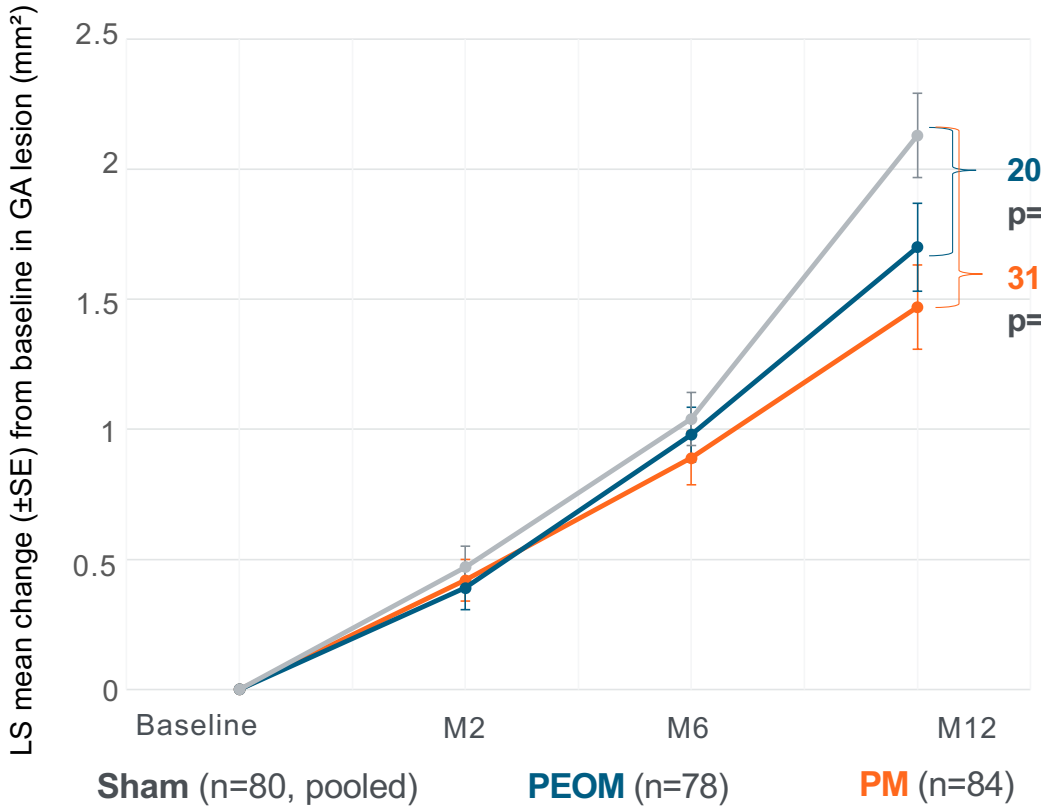
Number and severity of local and systemic treatment-emergent AEs

†Confirmed by the central reading center using fundus autofluorescence images. ‡Not counting the three satellite sites.

AE=adverse event; GA=geographic atrophy; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SEOM=sham every other month; SM=sham monthly.

Liao DS et al. *Ophthalmology* 2020;127:186–195.

# Pegcetacoplan reduced untransformed GA lesion growth rate in **FILLY**




**20% (every other month) reduction**
**p=0.064 vs sham***

**31% (monthly) reduction**
**p=0.004 vs sham***

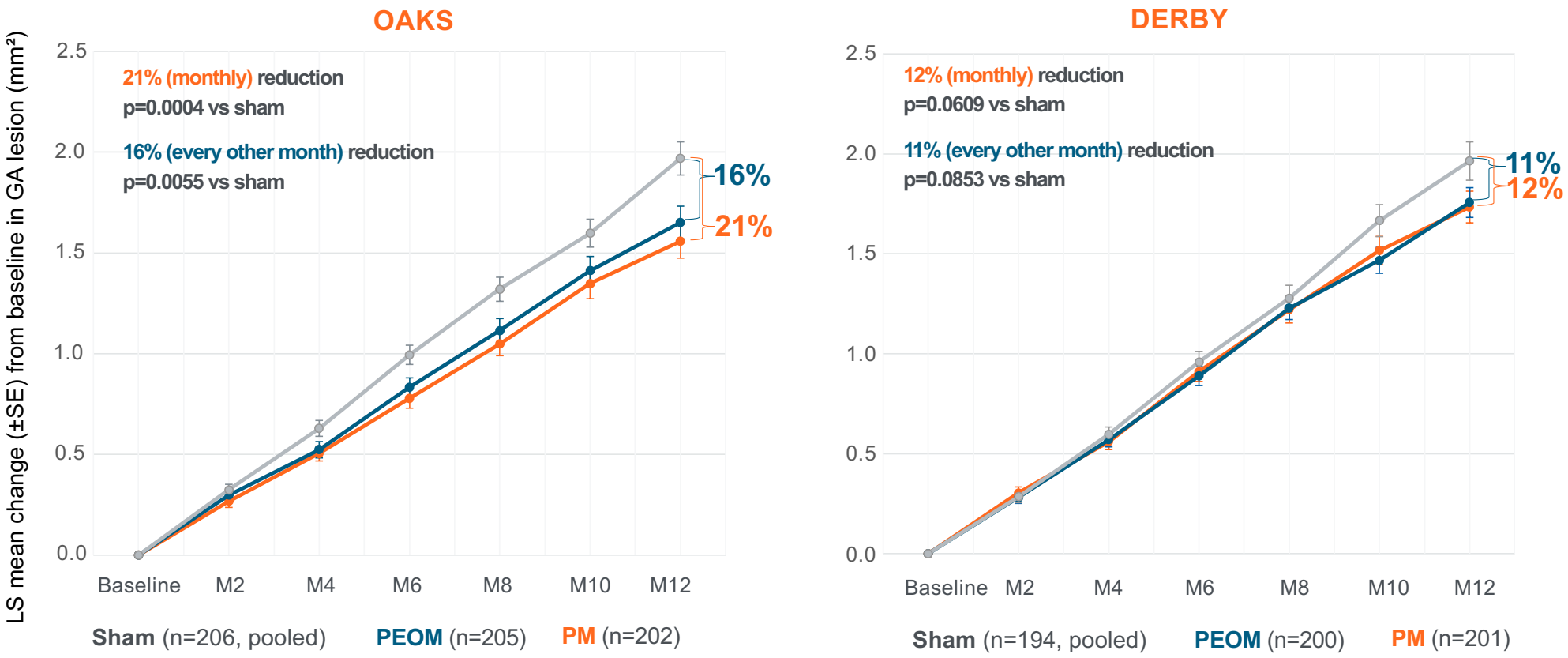
Change from baseline in untransformed lesion growth was a secondary endpoint in FILLY

*p<0.1 was the predefined threshold for statistical significance in FILLY.

GA=geographic atrophy; LS=least squares; M=Month; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.

Liao DS et al. *Ophthalmology* 2020;127:186–195.

# Pegcetacoplan monthly and every other month met the primary endpoint in **OAKS** but not **DERBY**

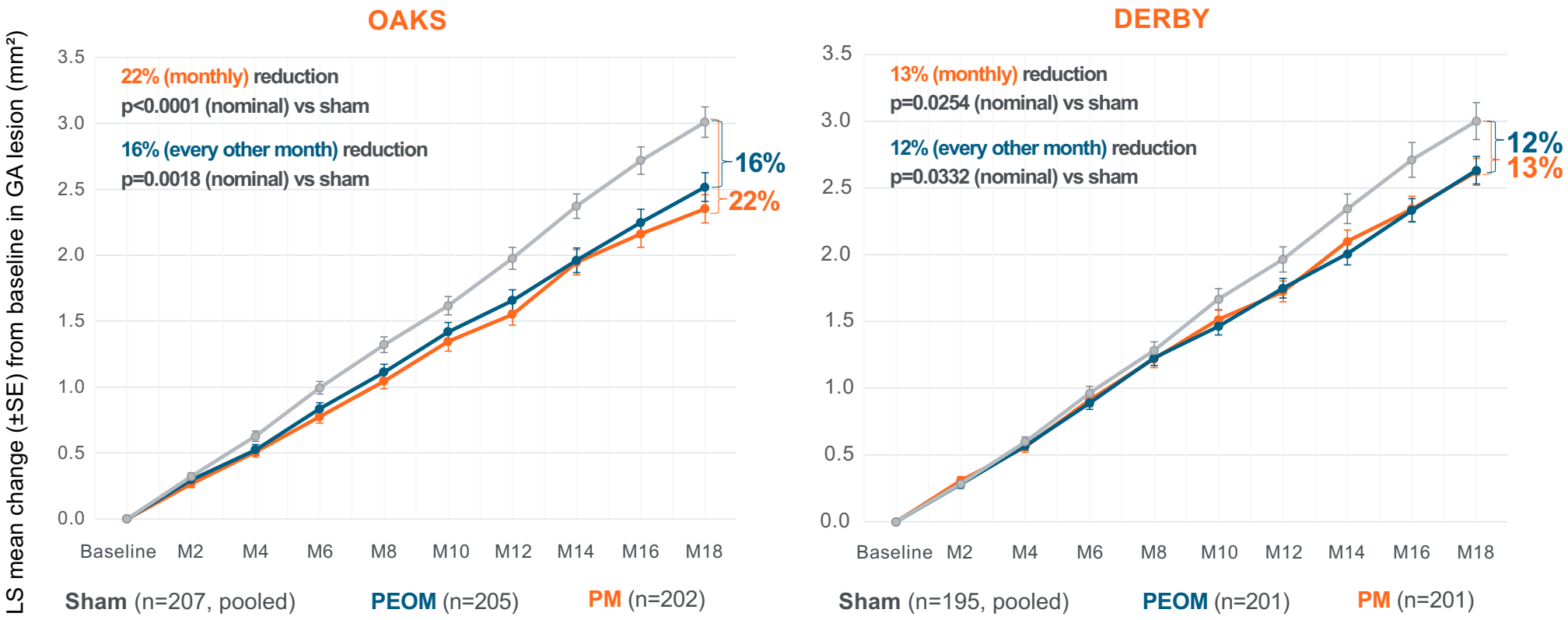



GA=geographic atrophy; LS=least squares; M=month; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.

Steinle N et al. Oral presentation at American Society of Retina Specialists (ASRS) 39th Annual Scientific Meeting, October 8–12, 2021, San Antonio, Texas, USA.

# Pegcetacoplan showed a sustained reduction in GA lesion growth vs sham in **OAKS** and **DERBY** at **Month 18**

OAKS DERBY




LS means estimated from a mixed-effects model for repeated measures. The mITT population was used for the analysis, defined as all randomized patients who received at least 1 injection of pegcetacoplan or sham and have baseline and at least 1 post-baseline value of GA lesion area in the study eye.

GA=geographic atrophy; LS=least squares; M=month; mITT=modified intent-to-treat; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.

# Methods

- In the original, pre-specified analysis, fellow eye CNV and baseline lesion size above/below 7.5mm$^2$ were clinically relevant covariates
- To investigate differences in the treatment effect estimate, a systematic covariate analysis was conducted
- Important clinical variables related to GA growth were defined and investigated for imbalance. The variables were compared across the 3 treatment arms via a chi-squared test (categorical) or ANOVA (continuous). Any variable with p<0.2 was included in the adjusted model
- The "common imbalance adjusted model" adjusts all imbalanced variables among the 3 studies to ensure the studies can be compared to one another

| | |
|---|---|
| **Study eye focality**<br>• Imbalanced in DERBY (*favoring sham*)<br>**Study eye lesion location**<br>• Imbalanced in OAKS (*favoring sham*)<br>**Study eye lesion size**<br>**Study eye pseudodrusen** | **Study eye low-luminance deficit**<br>• Imbalanced in FILLY (*favoring PM*)<br>**GA laterality**<br>**Study eye intermediate/large drusen**<br>• Imbalanced in DERBY (*favoring sham*) and FILLY (*favoring PM*)<br>**Region** |

All variables in red were adjusted for in all 3 studies (OAKS, DERBY, and FILLY)
"Favoring" indicates that the imbalance favors lower rate of progression in the stated study arm

ANOVA=analysis of variance; CNV=choroidal neovascularization; GA=geographic atrophy; PM=pegcetacoplan monthly.

# **OAKS and DERBY:** Selected demographics and baseline study eye characteristics

| | OAKS | | | DERBY | | |
|---|---|---|---|---|---|---|
| Characteristic | PM (N=202) | PEOM (N=205) | Sham pooled (N=207) | PM (N=201) | PEOM (N=201) | Sham pooled (N=195) |
| Bilateral GA, n (%) | 167 (82.7) | 174 (84.9) | 166 (80.2) | 164 (81.6) | 161 (80.1) | 150 (76.9) |
| Presence of CNV in fellow eye, n (%) | 43 (21.3) | 37 (18.0) | 43 (20.8) | 39 (19.4) | 41 (20.4) | 36 (18.5) |
| GA lesion size (FAF) $mm^2$, mean (SD) | 8.18 (3.89) | 8.30 (3.90) | 8.21 (3.71) | 8.37 (4.18) | 8.25 (3.89) | 8.24 (4.26) |
| Extrafoveal GA lesion location, n (%), | 86 (42.6) | 74 (36.1) | 60 (29.0) | 72 (35.8) | 81 (40.3) | 73 (37.4) |
| Unifocal GA lesion focality, n (%) | 59 (29.2) | 62 (30.2) | 68 (32.9) | 54 (26.9) | 53 (26.4) | 66 (33.8) |
| Intermediate/large drusen >20, n (%) | 93 (46.0) | 104 (50.7) | 104 (50.2) | 78 (38.8) | 78 (38.8) | 98 (50.3) |
| Pseudodrusen, present, n (%) | 167 (82.7) | 178 (86.8) | 173 (83.6) | 178 (88.6) | 181 (90.0) | 166 (85.1) |
| LLD (ETDRS letters), mean (SD) | 26.9 (16.92) | 25.9 (17.80) | 24.9 (17.38) | 27.5 (17.79) | 25.8 (16.49) | 25.7 (16.50) |
| BCVA score, mean letters (SD) | 61 (15.30) | 58.2 (17.03) | 57.6 (16.59) | 59.5 (17.40) | 58.7 (16.12) | 59.0 (16.85) |
| Median BCVA letter score (Snellen equivalent) | 63.0 | 61.0 | 60.0 | 62.0 | 61.0 | 60.0 |

These analyses were performed on the mITT population. The mITT population was defined as all randomized patients who received at least one injection of pegcetacoplan or sham and have baseline and at least 1 post-baseline value for GA lesion area in the study eye.

BCVA=best corrected visual acuity; CNV=choroidal neovascularization; ETDRS=Early Treatment Diabetic Retinopathy Study; FAF=fundus autofluorescence; GA=geographic atrophy; LLD=low-luminance deficit; mITT=modified intent-to-treat; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SD=standard deviation.

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# Baseline characteristics

| | PM (n=86) | PEOM (n=79) | Sham pooled (n=81) |
|---|---|---|---|
| Bilateral GA, n (%) | 71 (82.6) | 64 (81.0) | 72 (88.9) |
| History of CNV in fellow eye, n (%) | 36 (41.9) | 28 (35.4) | 29 (35.8) |
| GA lesion size, mean, $mm^2$ (SD) | 8.0 (3.8) | 8.9 (4.5) | 8.2 (4.1) |
| Extrafoveal GA lesion location, n (%) | 37 (44.0) | 26 (33.3) | 34 (42.5) |
| Unifocal GA lesion focality, n (%) | 21 (25) | 29 (37.2) | 27 (33.8) |
| Intermediate/large drusen >20, n (%)* | 43 (51.2) | 31 (39.7) | 31 (38.8) |
| BCVA score, mean letters (SD) | 59.8 (15.7) | 58.4 (16.0) | 59.8 (17.2) |
| Median BCVA letter score (Snellen equivalent) | 20/63 | 20/63 | 20/50 |
| LLD (ETDRS letters), mean letters (SD)* | 23.0 (14.3) | 27.3 (15.6) | 26.5 (17.1) |

These analyses were performed on the ITT population. *These analyses were performed on the mITT population. PM n=84; PEOM n=78; sham pooled = 80.
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Liao DS et al. *Ophthalmology* 2020;127:186–195.

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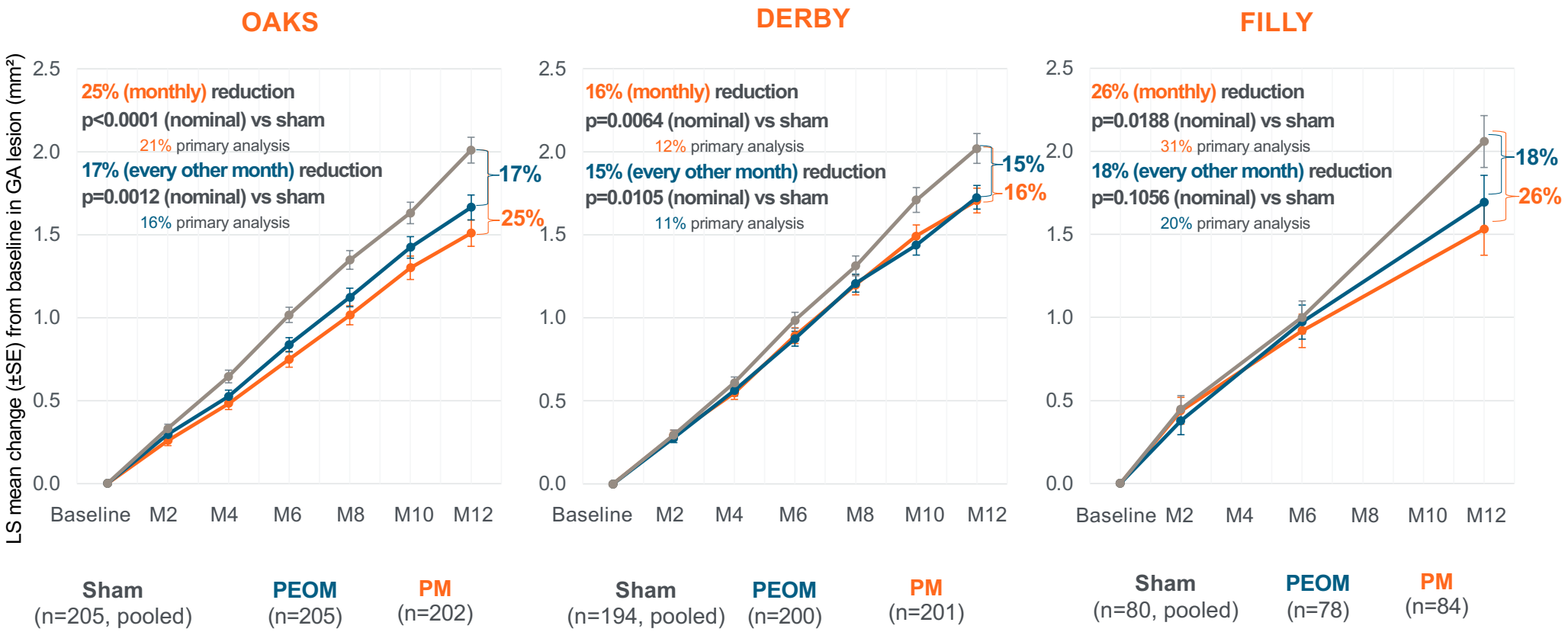
# Covariate Analysis

# Converging treatment effect of pegcetacoplan across OAKS, DERBY, and FILLY in covariate-adjusted post-hoc analysis at **Month 12**

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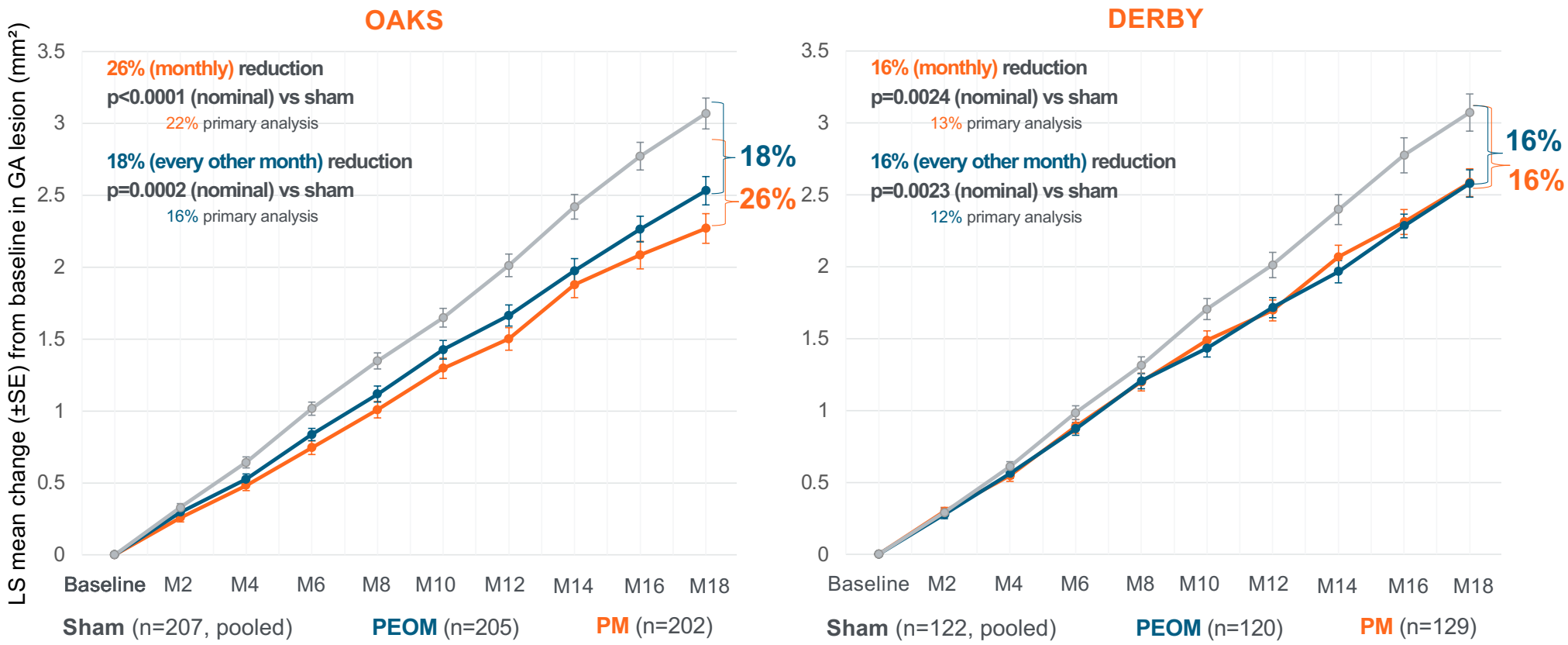
GA=geographic atrophy; LS=least squares; M=month; mITT=modified intent-to-treat; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.

# Converging treatment effect of pegcetacoplan in OAKS and DERBY in covariate-adjusted post-hoc analysis continues at **Month 18**

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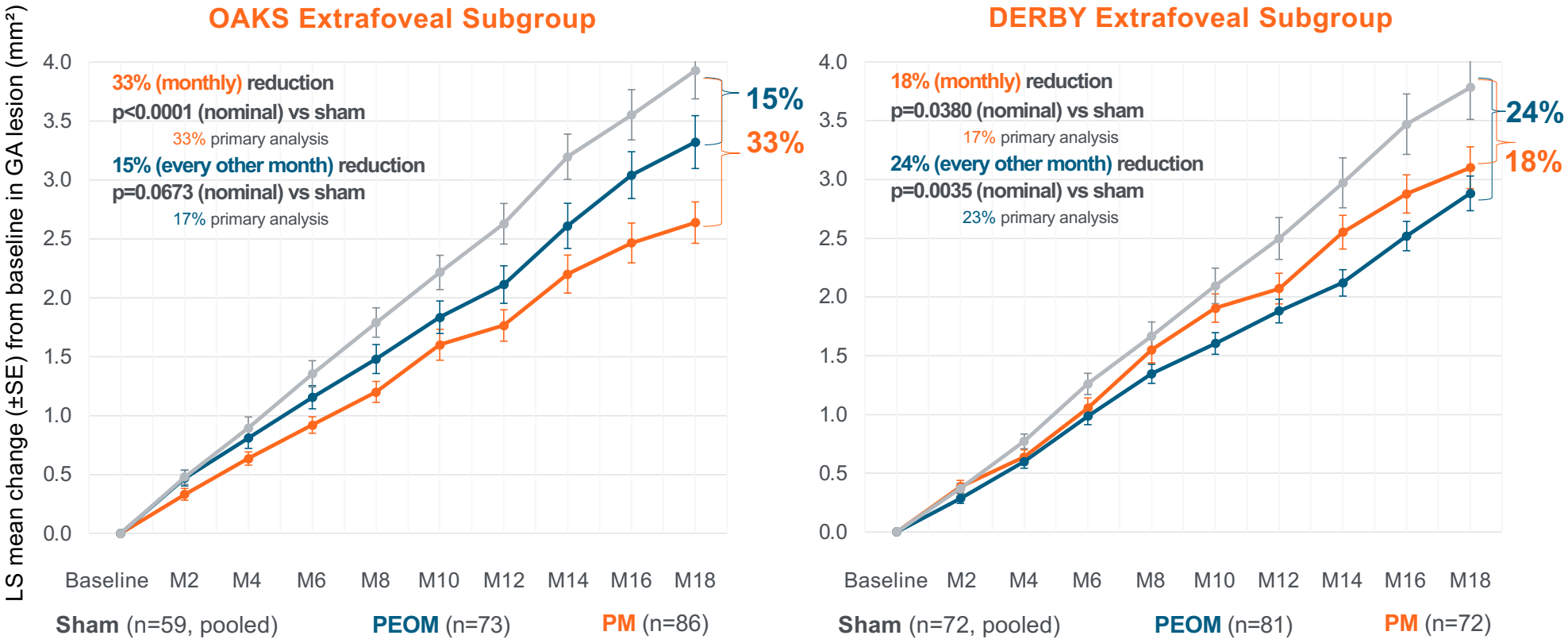
# Covariate-adjusted lesion growth in patients with extrafoveal lesions at Month 18

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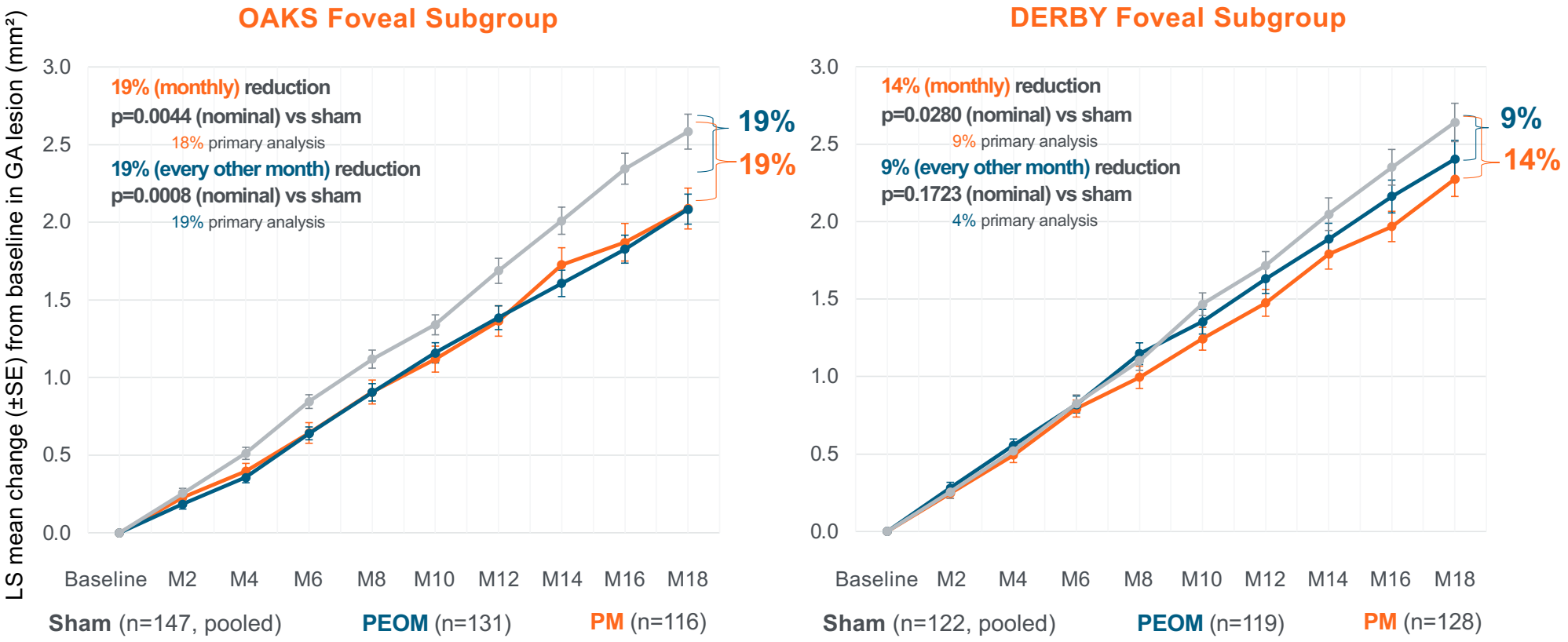
# Covariate-adjusted lesion growth in patients with foveal lesions at Month 18

OAKS DERBY

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# Conclusions

OAKS DERBY

- Covariate analysis indicated that DERBY was imbalanced on important factors related to GA growth that attenuated the effect in the primary analysis. In addition, an imbalance in OAKS was found in the lesion location that also attenuated the effect in the pegcetacoplan arms
- In a post-hoc analysis, after correcting for imbalances in baseline characteristics, OAKS and DERBY results are more convergent, including in the foveal and extrafoveal subgroups
- The OAKS post-hoc analysis supports the highly statistically significant results of the primary analysis, and the DERBY post-hoc analysis supports the confirmatory evidence demonstrated in OAKS
  - After adjusting for imbalances, results are more consistent across the studies, but this analysis does not fully explain the imbalances nor replace the primary analysis
- Future studies could consider incorporating additional variables as covariates and/or pre-specifying a plan for covariate adjustment
- The pegcetacoplan GA development program includes over 1500 patients across OAKS, DERBY, and FILLY, collectively demonstrating slowing of GA progression by pegcetacoplan monthly and every other month

GA=geographic atrophy.