Efficacy of intravitreal pegcetacoplan in patients with geographic atrophy (GA): 18-month results from the phase 3 OAKS and DERBY studies

Roger Goldberg, Jeffrey Heier, Charles Wykoff, Giovanni Staurenghi, Rishi P. Singh, Nathan Steinle, David Boyer, Jordi Mones, Frank G. Holz, Caleb Bliss, Federico Grossi, Ravi Metlapally, Ramiro Ribeiro

May 2nd, 2022
2022 ARVO Annual Meeting, Denver, Colorado
Disclosures

• Roger Goldberg has the following financial interests or relationships to disclose:
  • Consulting: AbbVie, Regeneron, Genentech/Roche, Apellis, Carl Zeiss Meditec, Boehringer Ingelheim, Apellis, Allergan
  • Research/Grant Support: Allergan/AbbVie, Aerie, Apellis, Boehringer Ingelheim, Carl Zeiss Meditec, Genentech/Roche, Graybug, NovoNordisk, Ocuphire, Unity Bio
  • Equity: Emmetrope Ophthalmics
  • Studies funded by Apellis Pharmaceuticals
Inhibition of the complement cascade provides a therapeutic target for GA

- Dysregulation of the complement cascade has been implicated in GA pathogenesis
- All 3 complement pathways end in the central cleavage of C3
- Pegcetacoplan is a 44 kDa pegylated highly-selective bi-cyclic peptide conjugated to a PEG polymer
- Inhibition of C3 blocks steps in the complement cascade needed for opsonization, inflammation, and formation of MAC

Figure adapted from Ricklin D, et al. Immunol Rev. 2016;274:33–58.
APC=antigen-presenting cell; GA=geographic atrophy; MAC=membrane attack complex.
Phase 2 FILLY results

- In the Phase 2 FILLY trial, pegcetacoplan resulted in statistically significant reductions in the growth of GA versus sham over 12 months, meeting the primary endpoint.

- **Phase 3 DERBY & OAKS objective:** to assess the efficacy and safety of multiple intravitreal injections of pegcetacoplan in patients with GA secondary to AMD.

*<p> was the predefined threshold for statistical significance in FILLY.
AMD=age-related macular degeneration; GA=geographic atrophy; LS=least square; M=Month; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.
Global phase 3 program: Design of studies (OAKS & DERBY)

Patients with GA secondary to AMD
~600 patients at ~200 sites globally in 2 studies (1,258 enrollees total)

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

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

Analysis Month 18
End of study at 24 months
• BCVA, LL-BCVA, low-luminance deficit
• Reading speed
• NEI VFQ-25
• FRI Index composite score
• Microperimetry (OAKS only) – Macular Integrity Assessment (MAIA) device

GALE open-label extension study (3 years)

AMD=age-related macular degeneration; BCVA=best corrected visual acuity; CNV=choroidal neovascularization; EOM=every other month; FRI=functional reading index; GA=geographic atrophy; LL=low luminance; MMRM=mixed-effect model for repeated measures; NEI-VFQ=National Eye Institute Visual Function Questionnaire-25.
These analyses were performed on the Month 18 modified intent-to-treat (mITT) population. The mITT population was 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.

ETDRS=Early Treatment Diabetic Retinopathy Study; GA=geographic atrophy; mm=millimeters; n=number of patients; NL-BCVA=normal luminance best-corrected visual acuity; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; ROW=rest of world; SD=standard deviation.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PM (N=202)</th>
<th>PEOM (N=205)</th>
<th>Sham Pooled (N=207)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>78.8 (7.24)</td>
<td>78.1 (7.74)</td>
<td>78.6 (7.25)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>125 (61.9%)</td>
<td>117 (57.1%)</td>
<td>133 (64.6%)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>77 (38.1%)</td>
<td>88 (42.9%)</td>
<td>73 (35.4%)</td>
</tr>
<tr>
<td>Geographic region</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA, n (%)</td>
<td>147 (72.8%)</td>
<td>142 (69.3%)</td>
<td>148 (71.5%)</td>
</tr>
<tr>
<td>ROW, n (%)</td>
<td>55 (27.2%)</td>
<td>63 (30.7%)</td>
<td>59 (28.5%)</td>
</tr>
<tr>
<td>Caucasian, n (%)</td>
<td>185 (91.6%)</td>
<td>189 (92.2%)</td>
<td>188 (90.8%)</td>
</tr>
<tr>
<td>GA lesion size (mm²), mean (SD)</td>
<td>8.18 (3.895)</td>
<td>8.30 (3.904)</td>
<td>8.21 (3.712)</td>
</tr>
<tr>
<td>Square root GA lesion size (mm), mean (SD)</td>
<td>2.78 (0.682)</td>
<td>2.80 (0.674)</td>
<td>2.79 (0.647)</td>
</tr>
<tr>
<td>GA lesion size, n (%)</td>
<td>&lt;7.5 mm²</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>101 (50.0%)</td>
<td>98 (47.8%)</td>
<td>104 (50.2%)</td>
</tr>
<tr>
<td>GA lesion location, n (%)</td>
<td>Extrafoveal</td>
<td>86 (42.6%)</td>
<td>74 (36.1%)</td>
</tr>
<tr>
<td>GA lesion focality, n (%)</td>
<td>59 (29.2%)</td>
<td>62 (30.2%)</td>
<td>68 (32.9%)</td>
</tr>
<tr>
<td>Intermediate/large drusen, n (%)</td>
<td>&gt;20</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>93 (46.0%)</td>
<td>104 (50.7%)</td>
<td>104 (50.2%)</td>
</tr>
<tr>
<td>Fellow eye CNV, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>43 (21.3%)</td>
<td>37 (18.0%)</td>
<td>43 (20.8%)</td>
</tr>
<tr>
<td>Study eye pseudodrusen (NIR), n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>167 (82.7%)</td>
<td>178 (86.8%)</td>
<td>173 (83.6%)</td>
</tr>
<tr>
<td>NL-BCVA (ETDRS letters), mean (SD)</td>
<td>61.0 (15.30)</td>
<td>58.2 (17.03)</td>
<td>57.6 (16.59)</td>
</tr>
</tbody>
</table>
These analyses were performed on the Month 18 modified intent-to-treat (mITT) population. The mITT population was defined as all randomised 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.

ETDRS=Early Treatment Diabetic Retinopathy Study; GA=geographic atrophy; mm=millimeters; n=number of patients; NL-BCVA=normal luminance best-corrected visual acuity; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; ROW=rest of world; SD=standard deviation.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PM (N=201)</th>
<th>PEOM (N=201)</th>
<th>Sham Pooled (N=195)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>78.7 (6.91)</td>
<td>79.2 (7.08)</td>
<td>78.6 (7.28)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>118 (58.7%)</td>
<td>120 (59.7%)</td>
<td>123 (63.1%)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>83 (41.3%)</td>
<td>81 (40.3%)</td>
<td>72 (36.19%)</td>
</tr>
<tr>
<td>Geographic region</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>USA, n (%)</td>
<td>142 (70.6%)</td>
<td>122 (60.7%)</td>
<td>122 (62.6%)</td>
</tr>
<tr>
<td>ROW, n (%)</td>
<td>59 (29.4%)</td>
<td>78 (39.3%)</td>
<td>73 (37.4%)</td>
</tr>
<tr>
<td>Caucasian, n (%)</td>
<td>187 (93.0%)</td>
<td>186 (92.5%)</td>
<td>188 (96.4%)</td>
</tr>
<tr>
<td>GA lesion size (mm²), mean (SD)</td>
<td>8.37 (4.181)</td>
<td>8.25 (3.894)</td>
<td>8.24 (4.261)</td>
</tr>
<tr>
<td>Square root GA lesion size (mm), mean (SD)</td>
<td>2.80 (0.722)</td>
<td>2.79 (0.678)</td>
<td>2.78 (0.734)</td>
</tr>
<tr>
<td>GA lesion size, n (%)</td>
<td>&lt;7.5 mm²</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>99 (49.3%)</td>
<td>98 (48.8%)</td>
<td>95 (48.7%)</td>
</tr>
<tr>
<td>GA lesion location, n (%)</td>
<td>Extrafoveal</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>72 (35.8%)</td>
<td>81 (40.3%)</td>
<td>73 (37.4%)</td>
</tr>
<tr>
<td>GA lesion focality, n (%)</td>
<td>Unifocal</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>54 (26.9%)</td>
<td>53 (26.4%)</td>
<td>66 (33.8%)</td>
</tr>
<tr>
<td>Intermediate/large drusen, n (%)</td>
<td>&gt;20</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>78 (38.8%)</td>
<td>78 (38.8%)</td>
<td>98 (50.3%)</td>
</tr>
<tr>
<td>Fellow eye CNV, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>39 (19.4%)</td>
<td>41 (20.4%)</td>
<td>36 (18.5%)</td>
</tr>
<tr>
<td>Study eye pseudodrusen (NIR), n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>178 (88.6%)</td>
<td>181 (90.0%)</td>
<td>166 (85.1%)</td>
</tr>
<tr>
<td>NL-BCVA (ETDRS letters), mean (SD)</td>
<td>59.5 (17.40)</td>
<td>58.7 (16.12)</td>
<td>59.0 (16.85)</td>
</tr>
</tbody>
</table>
At Month 12, Pegcetacopran monthly and every other month met the primary endpoint in OAKS but not DERBY.

LS means estimated from a mixed-effects model for repeated measures (MMRM). The modified intention-to-treat population was used for the analysis, defined as all randomized patients who received at least 1 injection of pegcetacopran 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 square; M=month; PEOM=pegcetacopran every other month; PM=pegcetacopran monthly; SE=standard error.
Pegcetacoplan reduced GA lesion growth vs sham in **OAKS** and **DERBY** at Month 18

LS means estimated from a mixed-effects model for repeated measures (MMRM). The modified intention-to-treat 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 square; **M** = month; **PEOM** = pegcetacoplan every other month; **PM** = pegcetacoplan monthly; **SE** = standard error.
In the combined analysis, pegcetacoplan reduced GA lesion growth vs sham at **Month 12**

**Sham** (n=400, pooled)  **PEOM** (n=405)  **PM** (n=403)

GA=geographic atrophy; LS=least squares; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly.
In the combined analysis, pegcetacoplan reduced GA lesion growth vs sham at Month 18.
Reductions in GA lesion growth in OAKS and DERBY over 6-month periods from baseline to Month 18

Percent reduction vs. sham pooled for Month 0 to Month 18 was estimated from a piecewise linear slope model with 6-month segments.

GA=geographic atrophy; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly.
Reductions in GA lesion growth in OAKS and DERBY combined over 6-month periods from baseline to Month 18

All data represented are from OAKS and DERBY combined

Percent reduction vs. sham pooled for Month 0 to Month 18 was estimated from a piecewise linear slope model with 6-month segments. GA=geographic atrophy; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly.
Pegcetacoplan reduced lesion growth in patients with extrafoveal lesions in a prespecified analysis at Month 12. Extrafoveal is defined as lesion with distance >0 to foveal center point.

LS means estimated from a mixed-effects model for repeated measures. The modified intention-to-treat population was used for the analysis.

GA=geographic atrophy; LS=least square; M=month; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.
Pegcetacoplan reduced lesion growth in foveal lesions in OAKS in a prespecified analysis at Month 12.

**OAKS**

- **16% (every other month)** reduction
  - $p=0.0165$ (nominal) vs sham
  - 16% (monthly) reduction
  - $p=0.0374$ (nominal) vs sham

**DERBY**

- **2% (every other month)** increase
  - $p=0.8419$ (nominal) vs sham
  - 6% (monthly) reduction
  - $p=0.4228$ (nominal) vs sham

Foveal was defined as lesion edge within center point of the fovea.

LS means estimated from a mixed-effects model for repeated measures. The modified intention-to-treat population was used for the analysis.

GA=geographic atrophy; LS=least square; M=month; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.
In the combined analysis, pegcetacoplan reduced **foveal** and **extrafoveal** lesion growth at **Month 12**

---

**Foveal**

- **11% (monthly)** reduction
  - p=0.0389 (nominal) vs sham
- **8% (every other month)** reduction
  - p=0.1219 (nominal) vs sham

**Extrafoveal**

- **26% (monthly)** reduction
  - p<0.0001 (nominal) vs sham
- **23% (every other month)** reduction
  - p=0.0002 (nominal) vs sham

---

Extrafoveal is defined as lesion with distance >0 to foveal center point.

LS means estimated from a mixed-effects model for repeated measures. The modified intention-to-treat population was used for the analysis.

GA=geographic atrophy; LS=least square; M=month; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.
Pegcetacoplan continued to show reduced lesion growth in patients with extrafoveal lesions at Month 18.

Extrafoveal is defined as lesion with distance >0 to foveal center point.

LS means estimated from a mixed-effects model for repeated measures. The modified intention-to-treat population was used for the analysis.

Sham (n=60, pooled) PEOM (n=74) PM (n=86)
Sham (n=73, pooled) PEOM (n=81) PM (n=72)

GA=geographic atrophy; LS=least square; M=month; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.
Pegcetacoplan reduced lesion growth in patients with foveal lesions at Month 18

Foveal was defined as lesion edge within center point of the fovea.

LS means estimated from a mixed-effects model for repeated measures. The modified intention-to-treat population was used for the analysis.

GA=geographic atrophy; LS=least square; M=month; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.
In the combined analysis, pegcetacoplan reduced foveal and extrafoveal lesion growth at Month 18.

**Foveal**
- 13% (monthly) reduction
  - $p=0.0070$ (nominal) vs sham
- 13% (every other month) reduction
  - $p=0.0069$ (nominal) vs sham

**Extrafoveal**
- 26% (monthly) reduction
  - $p<0.0001$ (nominal) vs sham
- 21% (every other month) reduction
  - $p=0.0006$ (nominal) vs sham

---

Sham (n=269, pooled)  PEOM (n=251)  PM (n=245)

Sham (n=133, pooled)  PEOM (n=155)  PM (n=158)

Foveal was defined as lesion edge within center point of the fovea. LS means estimated from a mixed-effects model for repeated measures. The modified intention-to-treat population was used for the analysis.

GA=geographic atrophy; LS=least square; M=month; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; SE=standard error.
18 Month Safety
Overall TEAEs at 18 months

<table>
<thead>
<tr>
<th></th>
<th>OAKS PM (N=213)</th>
<th>PEOM (N=212)</th>
<th>Sham Pooled (N=211)</th>
<th>DERBY PM (N=206)</th>
<th>PEOM (N=208)</th>
<th>Sham Pooled (N=206)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All TEAEs, n (%)</td>
<td>185 (86.9%)</td>
<td>177 (83.5%)</td>
<td>169 (80.1%)</td>
<td>170 (82.5%)</td>
<td>171 (82.2%)</td>
<td>164 (79.6%)</td>
</tr>
<tr>
<td>Total events, M</td>
<td>1037</td>
<td>965</td>
<td>893</td>
<td>993</td>
<td>835</td>
<td>734</td>
</tr>
<tr>
<td>Ocular TEAEs in study eye</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients, n (%) M</td>
<td>126 (59.2%) 325</td>
<td>114 (53.8%) 270</td>
<td>88 (41.7%) 199</td>
<td>118 (457.3%) 308</td>
<td>99 (47.6%) 216</td>
<td>84 (40.8%) 151</td>
</tr>
<tr>
<td>Non-ocular TEAEs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients, n (%) M</td>
<td>152 (71.4%) 573</td>
<td>158 (74.5%) 567</td>
<td>144 (68.2%) 559</td>
<td>148 (71.8%) 567</td>
<td>132 (63.5%) 495</td>
<td>131 (63.6%) 485</td>
</tr>
<tr>
<td>Serious ocular TEAEs in the study eye, n (%) M</td>
<td>5 (2.3%) 5</td>
<td>4 (1.9%) 4</td>
<td>0</td>
<td>4 (1.9%) 4</td>
<td>0</td>
<td>2 (1.0%) 2</td>
</tr>
<tr>
<td>Optic ischemic neuropathy</td>
<td>2 (0.9%) 2</td>
<td>0</td>
<td>0</td>
<td>1 (0.5) 1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Papilledema</td>
<td>1 (0.5%) 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Retinal tear</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (0.5) 1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Retinal detachment</td>
<td>0</td>
<td>1 (0.5%) 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Endophthalmitis a</td>
<td>2 (0.9%) 2</td>
<td>3 (1.4%) 3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Vitritis</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2 (1.0%) 2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dry AMD</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (0.5%) 1</td>
</tr>
<tr>
<td>Macular hole</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (0.5%) 1</td>
</tr>
</tbody>
</table>

Note: Sham patients do not receive injections.

The events of endophthalmitis include infectious and noninfectious endophthalmitis.

Any AEs with missing or unknown severity were considered as severe. The safety population was used for this analysis.

AE=adverse event; AMD=age-related macular degeneration; M=number of events; n=number of patients; PEOM=pegcetacoplan every other month; PM=pegcetacoplan monthly; TEAE=treatment-emergent AE.
eAMD findings from FILLY informed the design of the Phase 3 program

- If eAMD suspected by the Investigator, prespecified imaging (CFP, OCT, FA & OCTA [select sites]) captured

- Patients remain on study treatment and also treated with anti-VEGF pharmacotherapy per protocol
  - Initiation of anti-VEGF therapy for eAMD is at the discretion of the investigator and is not reading-center determined

- Within the reporting from OAKS and DERBY
  - Reports of eAMD include all adverse events reported by the investigator falling within the preferred terms neovascular AMD or CNV, regardless of reading center confirmation

AMD=age-related macular degeneration; CFP=color fundus photography; CNV=choroidal neovascularization; eAMD=exudative AMD; FA=fundus autofluorescence; OCT=optical coherence tomography; OCTA=OCT angiography; VEGF=vascular endothelial growth factor.
Investigator-reported events of eAMD at Month 18

<table>
<thead>
<tr>
<th>COMBINED STUDIES</th>
<th>PM (N=419)</th>
<th>PEOM (N=420*)</th>
<th>Sham Pooled (N=417)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator-determined new-onset eAMD, %</td>
<td>40 (9.5%)</td>
<td>26 (6.2%)</td>
<td>12 (2.9%)</td>
</tr>
<tr>
<td>Rate of eAMD per 100 patient-years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Month 12</td>
<td>6.6</td>
<td>4.4</td>
<td>2.6</td>
</tr>
<tr>
<td>Month 18</td>
<td>7.4</td>
<td>4.6</td>
<td>2.2</td>
</tr>
</tbody>
</table>

- Investigator-determined new-onset eAMD at Month 12 was reported in 6.0%, 4.1%, and 2.4% of patients in PM, PEOM, and sham, respectively
- Additional cases of MNV were detected by reading center on Month 12 FA (2 PM, 4 PEOM, and 6 sham pooled) and the next protocol-specified FA is at Month 24
- Majority of events were classified as occult>Type 1 MNV on FA taken at time of exudation

*Events include preferred terms of choroidal neovascularization and neovascular AMD.
*One patient had CNV on medical history in study eye and is not counted in the denominator for this analysis. 211 patients were at risk of new-onset eAMD.
AE=adverse event; AMD=age-related macular degeneration; eAMD=exudative AMD; FA=fluorescein angiography; MNV=macular neovascularization; n=number of patients; PEOM=pegcetacoplan every other month; PM=pegcetacoplan every month.
Safety profile of pegcetacoplan in DERBY and OAKS (pooled) at 18 months

• **Intraocular inflammation:**
  – Over 18 months, 21 events of intraocular inflammation were observed in 18 patients. The rate of intraocular inflammation was 0.23% per injection (as compared to 14 events in 13 patients and 0.22% per injection at month 12).
    • This total includes four cases that were reported in 2018 and linked to a drug impurity, one of which was an event of non-infectious endophthalmitis. The rate of intraocular inflammation over 18 months was 0.19% per injection if these four 2018 cases attributable to drug impurity from the 2018 drug lot are excluded

• **Infectious endophthalmitis:**
  – There were 4 cases of infectious endophthalmitis across the PM and PEOM arms
    • 2 confirmed, 2 suspected
    • 0.044% per injection (9,145 total injections)

• **Additional:**
  – No cases of retinitis or vasculitis (occlusive or nonocclusive) were reported

---
eAMD=exudative age-related macular degeneration; IOI=intraocular inflammation; IP=investigational product; IVT=intravitreal; PEOM=pegcetacoplan every other month; PPV=pars plana vitrectomy; PM=pegcetacoplan monthly; VEGF=vascular endothelial growth factor.
Conclusions

- Pegcetacoplan showed continued reductions in lesion growth from baseline to Month 18 in both studies (all nominal p-values < 0.05)

- Pegcetacoplan demonstrated efficacy in patients with foveal and extrafoveal lesions

- Pegcetacoplan was well-tolerated through Month 18
  - 9.5%, 6.2%, and 2.9% of patients in the combined PM, PEOM, and sham groups experienced new-onset investigator-determined eAMD over 18 months
  - Patients who developed eAMD continued treatment with pegcetacoplan and received anti-VEGF therapy
  - Rate of IOI was 0.23% per injection
  - Rate of infectious endophthalmitis was 0.044% per injection, in line with previous prospective pivotal trials of intravitreal therapeutics

- The pegcetacoplan GA development program includes over 1,500 patients across OAKS, DERBY, and FILLY, collectively demonstrating slowing of GA progression by pegcetacoplan monthly and every other month

GA=geographic atrophy.