# Abstract 98

## SAFETY OF INTRAVITREAL PEGCETACOPLAN IN GEOGRAPHIC ATROPHY: 24-MONTH RESULTS FROM THE OAKS AND DERBY PHASE 3 TRIALS

Oral

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**Purpose:**

To report the final 24-month safety results of two phase 3, randomized, double-masked, sham-controlled clinical trials comparing the efficacy and safety of monthly or every-other-month (EOM) intravitreal pegcetacoplan with sham in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

**Methods:**

Included patients are ≥60 years old, have best-corrected visual acuity ≥24 letters, and GA area between 2.5 and 17.5 mm2; if multifocal GA was present at baseline, at least one focal lesion must be ≥1.25 mm2. Enrollment was completed in July 2020. The primary endpoint was change in GA lesion size measured by fundus autofluorescence from baseline to Month 12. Secondary endpoints, including functional outcomes, were measured up to Month 24. Key safety measures include incidences of ocular and systemic adverse events, and incidence of new-onset exudative AMD (eAMD) in the study eye.

**Results:**

At Month 12, the primary endpoint was met in OAKS but not in DERBY. Overall, pegcetacoplan was well tolerated with ocular treatment-emergent adverse events generally considered mild or moderate. The rate of eAMD was higher in pegcetacoplan-treated patients (6.0% monthly, 4.1% EOM arm) vs sham (2.4%). The rates of infectious endophthalmitis and intraocular inflammation per injection were 0.047% and 0.22%, respectively. The safety profile of pegcetacoplan at 18 months was consistent with that reported at 12 months. The 24-month safety data, including overall adverse events, new-onset eAMD, infectious endophthalmitis, and intraocular inflammation will be presented here.

**Conclusions:**

Pegcetacoplan was generally safe and well tolerated at Months 12 and 18. Twenty-four-month safety data will be presented.