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EFFICACY 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 final 24-month efficacy 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.

Methods:

Patients are ≥60 years old, have best-corrected visual acuity (BCVA) ≥24 letters, and GA area between 2.5–17.5mm2 or one focal lesion ≥1.25mm2 if multifocal GA was present at baseline. Change in GA lesion size, as measured by fundus autofluorescence, from baseline to Month 12 (primary endpoint) and from baseline to Month 24 were assessed. Other key endpoints at Month 24 include reading speed; mean Functional Reading Independence index score and normal luminance-BCVA. Additionally, change from baseline in mean threshold sensitivity was assessed by microperimetry at Month 24 in OAKS.

Results:

The primary efficacy endpoint at Month 12 was met in OAKS but not DERBY. At Month 12, OAKS showed a statistically significant reduction in GA lesion growth vs sham in the monthly and EOM arms by 21% (p=0.0004) and 16% (p=0.0055), respectively. DERBY did not reach statistical significance; pegcetacoplan decreased GA lesion growth vs sham by 12% (p=0.0609, monthly) and 11% (p=0.0853, EOM). Month 18 data were generally consistent with Month 12 data, with effects in DERBY over Months 6–18 more closely resembling those in OAKS. Final 24-month efficacy results from OAKS and DERBY will be presented here.

Conclusions:

Pegcetacoplan met the primary endpoint in OAKS, demonstrating a significant reduction in GA lesion growth compared with sham. In DERBY, the reduction in GA lesion growth did not meet statistical significance. Twenty-four-month efficacy results will be presented here.