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2024 AAO Retina Subspecialty Day

SAGA efficacy and safety results

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TITLE: Gildeuretinol in Geographic Atrophy: Results from SAGA, a 2-year, Randomized, Double-masked, Placebo-controlled Study

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ABSTRACT BODY (1000 characters max without spaces)

Purpose: Gildeuretinol acetate, a novel deuterated vitamin A, is an investigational treatment for age-related macular degeneration (AMD).

Methods: SAGA (NCT03845582) is a 24-month, double-masked, randomized, placebo-controlled trial. Participants with geographic atrophy (GA) secondary to AMD in at least one eye were randomized 2:1 to gildeuretinol 14 mg/day:placebo. Primary efficacy endpoint was growth rate of GA lesions from baseline to 24 months. First key secondary endpoint was change in low luminance visual acuity (LLVA) over 24 months.

Results: Baseline characteristics were similar among groups. Mean growth rate (mm²/yr, SE) at 24 months was 0.25 mm²/yr slower in the gildeuretinol group (1.62, 0.081) vs. placebo (1.87, 0.116), p=0.075. Sensitivity analysis of growth rate (mm²/year, SE) from 6 to 24 months showed a mean difference of 0.29 mm²/yr in the gildeuretinol group (1.61, 0.082) vs. placebo (1.90, 0.120), p=0.047. At 24 months, LLVA loss was 4.4 letters less in the gildeuretinol group vs. placebo, (p=0.031). Majority of AEs were mild or moderate; serious AEs were similar among groups.

Conclusion: Oral gildeuretinol was associated with slower growth of GA lesions and improved visual acuity.

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