

Topical OT-551 for Treating Geographic Atrophy: Phase II Results

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Abstract

Purpose: : To determine if treatment with OT-551 reduces progression of the the area of geographic atrophy (GA) in subjects with GA associated with age-related macular degeneration (AMD).

Methods: : A randomized, double-masked, multi-center, placebo-controlled, clinical trial of OT-551 (0.3% & 0.45%) in 137 subjects with GA was performed. The study eye was required to have ≥ 1 discrete areas of GA of $\geq 1.3 \text{ mm}^2$ (0.5 disc area [DA]) and a total GA area of 1.3 to 17.8 mm^2 (0.5 - 7.0 DA) that is within 3000 microns of the foveal center. Topical OT-551 was administered to only one qualifying eye 4X daily for up to 2 years. Visits were scheduled at screening, baseline (BL), and at 1, 3, 6, 9, 12, 15, 18, 21 & 24 months. Efficacy outcomes included changes from BL in total area of GA and best-corrected visual acuity (BCVA) score. Safety measures were assessed by complete ophthalmologic examination and review of ocular and systemic adverse events (AEs).

Results: : At BL, the mean (median) area of GA in study eyes from digital fluorescein angiograms was $6.17 (6.26) \text{ mm}^2$ in the vehicle placebo group, $6.26 (5.72) \text{ mm}^2$ in the OT-551 0.3% group, and $6.04 (5.11) \text{ mm}^2$ in the OT-551 0.45% group. At month 18, mean (median) changes from BL of $+3.55 (+3.08) \text{ mm}^2$ in the placebo group, $+3.01 (+2.91) \text{ mm}^2$ in the OT-551 0.3% group, and $+3.43 (+2.70) \text{ mm}^2$ in the OT-551 0.45% group were observed. Mean (median) changes in BCVA at 18 months in study eyes were -4.9 (-3.0) letters in the placebo group, -8.9 (-6.0) letters in the OT-551 0.3% group, and -7.7 (-5.0) letters in the OT-551 0.45% group. The proportion of subjects losing ≥ 15 letters at month 18 was 16% in the

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placebo group, 20% in the OT-551 0.3% group and 21% in the OT-551 0.45% group. Most reported AEs were non-serious, mild in severity, and occurred at a low incidence (<5%). All serious AEs were non-ocular and none were related to the study drug.

Conclusions: : While concentrations of OT-551 up to 0.45% appear to be safe when dosed 4X daily for up to two years, OT-551 does not appear to reduce the progression of the area of GA in subjects with AMD.

Clinical Trial: : www.clinicaltrials.gov NCT00485394

Keywords: age-related macular degeneration • clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials • antioxidants

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