Assessment of Progression of Geographic Atrophy in the FILLY Study

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Purpose:
To further assess progression of geographic atrophy (GA) by categories of change in GA in eyes receiving treatment with APL-2 or sham.

Methods:
The FILLY trial was a Phase 2 multicenter, randomized, single-masked, sham-controlled clinical trial of APL-2 in patients with GA. Intravitreal injection of APL-2 was administered in the study eye monthly (M) or every other month (EOM) for 12 months. The primary efficacy endpoint was the change in square root GA lesion size from baseline to Month 12 compared to sham. Post hoc analysis was conducted to assess progression of GA (change in square root of GA lesion size from baseline) by quartiles in the overall dataset as well as by treatment groups. Only patients with observed data at Month 12 were included.

Results:
Of 246 patients enrolled, 192 had efficacy endpoint observations at Month 12 and were included in this analysis. The overall mean change in GA lesion size was 1.46 (p< 0.05), 1.63 (p= 0.067), 2.19 mm in the M (n=67), EOM (n=58) and sham (S) (n=67), respectively. The quartile distribution (change from baseline GA lesion size) for the overall patient population was as follows: Q1: <0.13, Q2: 0.13-<0.27, Q3: 0.27-<0.41, Q4: >0.41 mm. Proportion of patients in each treatment group by quartile were: Q1 (M: 27%; EOM: 35%; S: 15%); Q2 (M: 30%; EOM: 28%; S: 18%); Q3 (M: 24%; EOM: 17%; S: 33%); Q4 (M: 19%; EOM: 21%; S: 34%). When assessed by each treatment group, quartile distributions demonstrated a shift in the sham group compared to the APL-2 treatment arms (Q1: <0.12 for M, <0.11 for EOM and <0.21 mm for S; Q4: >0.37 for M, >0.36 for EOM and >0.47 mm for S).

Conclusions:
Consistent with the overall results, the proportion of patients with relatively smaller change in lesion size was higher in the APL-2 treatment arms compared to the sham control group suggestive of APL-2 control over GA progression. This finding was further supported by accelerated progression of GA lesion size in the sham group compared to the APL-2 groups.