Patients with bilateral geographic atrophy secondary to age-related macular degeneration were randomized in a 2:2:1 ratio to Brimo DDS 132 µg (n = 49), Brimo DDS 264 µg (n = 41), or sham procedure (n = 23) administered in the study eye at day 1 and month 6. All fellow eyes received sham procedure at day 1 and month 6. Geographic atrophy lesion area was assessed by stereoscopic fundus photography and fluorescein angiography at the screening visit (day -21 to -1) and at study visits at months 3, 6, 9, 12, 18, and 24. Additional follow-up visits were scheduled at months 1, 4, 5, 7, 8, 10, and 11. Also, safety visits (not shown) were scheduled on day 7 after each treatment, and follow-up telephone calls to collect adverse event reports were made on days 2 and 14 after each treatment and at months 15 and 21. The primary endpoint was the change in geographic atrophy lesion area from baseline at month 12, as determined by masked readers of fundus photography and fluorescein angiography digital images at a central reading center. The geographic atrophy lesion area measured at the screening visit was considered the baseline value. The study was not powered to detect statistically significant differences between treatment groups.

Brimo DDS, brimonidine drug delivery system; Scr, screening visit.