Abicipar Phase 2 MAPLE Trial Demonstrates Improved Safety for Patients with nAMD Following a Modified Manufacturing Process

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Purpose:
MAPLE evaluated the safety of intravitreal injections of abicipar 2 mg produced using a modified manufacturing process, in patients with neovascular age-related macular degeneration (nAMD). 11 eyes developed intraocular inflammation (IOI) after injection and were exited from the trial. This study describes the presentations, treatments, courses and outcomes of all 11 patients with regard to vision, central retinal thickness, and any other adverse events.

Methods:
MAPLE was a Phase 2, multicenter, open-label, single-arm 28-week study. Enrolled patients (age ≥ 50, n=123) with nAMD were treatment-naïve (67.5% of subjects) or had prior anti-vascular endothelial growth factor treatments (32.5% of patients; excluding prior abicipar) and best-corrected visual acuity (BCVA) between 24 (20/320) and 78 letters (20/32) in the study eye. Patients received abicipar 2 mg at baseline, weeks 4, 8, 16 and 24. Safety was assessed at all visits. 11 patients were discontinued from the study due to IOI and we retrospectively evaluated their entire clinical courses including assessments of pre and post-treatment visual and anatomic changes, treatments, and other clinical characteristics.

Results:
The overall incidence of treatment-related IOI of any severity was 8.9% (11/123). IOI was diagnosed after 1 injection in 3 study eyes, 2 injections in 2, and 4 injections in 6. Nine cases were assessed as mild (2.4% [3/123]) or moderate (4.9% [6/123]) in severity. Severe IOIs were reported in 1.6% (2/123) of study eyes with 1 case of iritis and 1 case of uveitis. All cases were treated with topical corticosteroids, 4 cases with moderate and/or severe IOI also received oral or intraocular steroids. After study completion, all IOI cases completely resolved with intraocular pressure returned to normal range, and overall vision in the majority of patients recovered to slightly better than baseline. There were no reported cases of endophthalmitis or retinal vasculitis in this study.

Conclusions:
In this phase 2 trial safety trial, 11 patients developed IOI. At the final visit, BCVA had improved in most eyes and inflammation completely resolved in all eyes. Abicipar produced through a modified manufacturing process demonstrated much improved safety compared with the abicipar used in the combined Phase 3 studies.