Evaluation of Lotilaner Ophthalmic Solution, 0.25% in Severe Demodex Blepharitis

Purpose:
The phase 3 Saturn-2 prospective clinical trial evaluated the efficacy and safety of a 6-week treatment with lotilaner ophthalmic solution, 0.25% in treating Demodex blepharitis (DB). Patients with moderate to severe DB at baseline were enrolled in the study. This is a subset analysis of patients with severe DB. The aim is to evaluate the proportion of patients with severe DB who achieved a clinically meaningful collarette reduction (CMCR) to ≤10 collarettes following the 6-week treatment with lotilaner ophthalmic solution, 0.25%.

Methods:
In the Saturn-2 clinical trial, patients with DB were randomly assigned in a 1:1 ratio to receive either lotilaner ophthalmic solution, 0.25% (study group) or vehicle (control group) twice daily for 6 weeks. Severe DB, for this analysis, was classified as having collarette Grade 3 (≥1/3 to <2/3 of the lashes) or Grade 4 (≥2/3 of the lashes) at baseline. CMCR to ≤10 collarettes was defined as achieving Grade 0 or 1 (≤10 lashes of the upper eyelid of the analysis eye with collarettes) at Day 43.

Results:
A total of N=131 patients in the study group and N=145 in the control group had severe DB (collarette Grade 3 or 4) at baseline. After 6 weeks of treatment, the proportion of Grade 3 eyes that achieved CMCR to ≤10 collarettes in the study group was statistically significantly higher than in the control group (87.0% vs. 28.8%, $p<0.0001$). Similarly, the proportion of Grade 4 eyes that achieved CMCR to ≤10 collarettes is 85.4% in the study group vs 12.1% in the control group ($p<0.0001$) on Day 43.

Conclusions:
Lotilaner ophthalmic solution, 0.25% is currently under evaluation for the treatment of DB in humans. The analysis of patients with severe DB in Saturn-2 clinical trial shows that twice-daily treatment with lotilaner ophthalmic solution, 0.25% for 6 weeks statistically significantly reduced collarettes to clinically meaningful collarette reduction to ≤10 collarettes in patients with severe DB.

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