Safety & Efficacy of Lotilaner Ophthalmic Solution, 0.25% in Treating *Demodex* Blepharitis: Results of the Saturn-2, Pivotal, Phase III Trial

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PURPOSE

To evaluate the safety and efficacy of lotilaner ophthalmic solution, 0.25% (TP-03, Tarsus Pharmaceuticals) for the treatment of *Demodex* blepharitis (DB).

METHODOLOGY

Subject Demographic

- ≥ 18 years old
- N = 412 patients
  - N = 203 in TP-03
  - N = 209 in vehicle

Study Design

- Randomized, controlled, double-masked study of TP-03 vs vehicle control twice daily for 43 days
- Inclusion criteria:
  - > 10 upper lashes with collarettes
  - ≥ mild upper lid margin erythema
  - ≥ 1.5 mites/lash on upper/lower lids combined in at least 1 eye

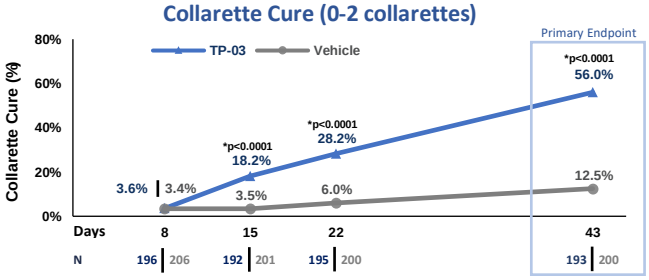
Study Site(s)

- 21 US eye care centers

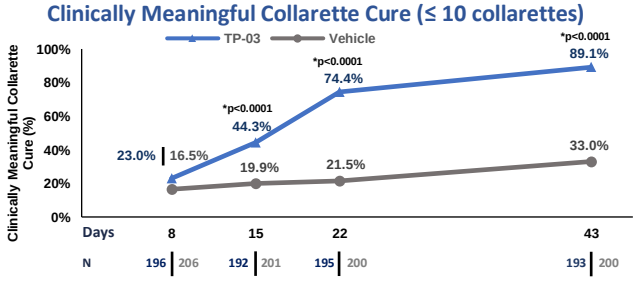
FINDINGS

See the graphs below that highlight the primary and secondary endpoints, and other key findings in the effects of 43-day therapy with TP-03 vs vehicle in treating DB.

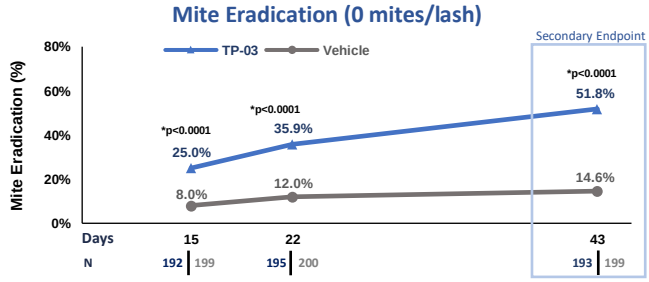
Collarette Cure (0-2 collarettes)



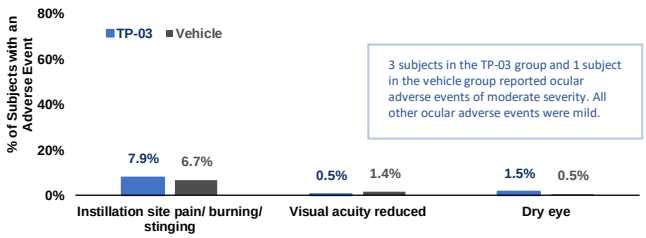
Clinically Meaningful Collarette Cure (≤ 10 collarettes)



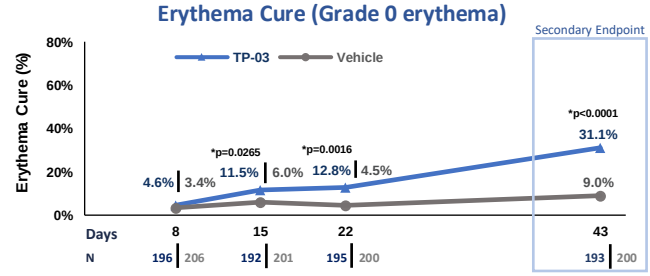
Mite Eradication (0 mites/lash)



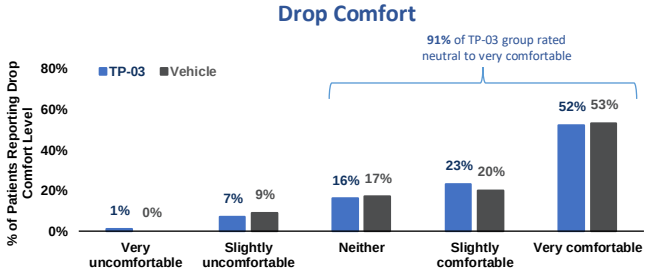
Treatment-Related Ocular AE Rates > 1%



Erythema Cure (Grade 0 erythema)



Drop Comfort



CONCLUSION

Results of Saturn-2, pivotal, Phase III trial demonstrated that **lotilaner ophthalmic solution, 0.25% met the primary and all secondary endpoints**; was well tolerated with no serious treatment-related adverse events occurred.