Extended Observational Safety Trial to Evaluate the Long-Term Safety of Lotilaner Ophthalmic Solution, 0.25% for the Treatment of *Demodex* Blepharitis

Saturn-1 Extension Study

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PURPOSE

To evaluate the long-term efficacy and safety of lotilaner ophthalmic solution, 0.25% (TP-03, Tarsus Pharmaceuticals) after the completion of a 6-week treatment for *Demodex* blepharitis

METHODOLOGY

Study Subjects

- 421 patients were randomized 1:1 to receive TP-03 or vehicle twice daily for 6 weeks in Saturn-1 study.
- 239 and 220 patients were evaluated on days 180 and 365, respectively in the extension study.

Study Design

- Observation study extended from the Phase 2b/3 randomized, vehicle-controlled, double-masked Saturn-1 study.
- Patients were evaluated on days 180 and 365 after the initiation of a 6-week BID treatment with TP-03 or vehicle control.
- Efficacy and safety measurements were evaluated.

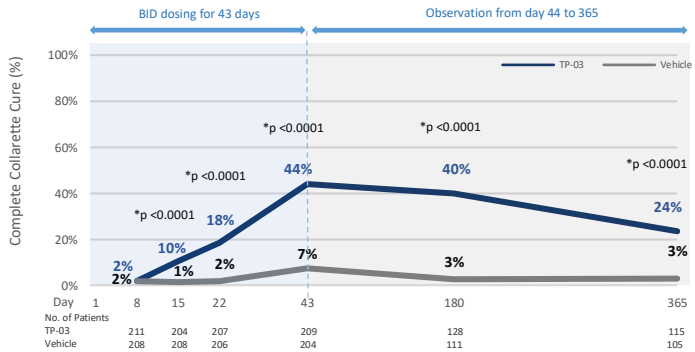
Study Site(s)

- Saturn-1 was conducted at 15 US eye care centers.

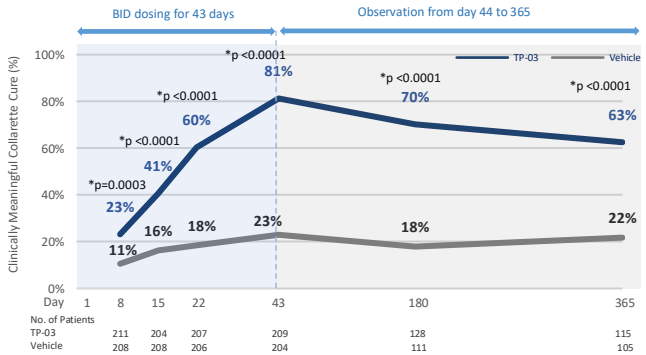
FINDINGS

See the graphs below that highlight key findings on **days 180 and 368** after receiving TP-03 vs vehicle for *Demodex* Blepharitis.

Complete Collarette Cure (0-2 collarettes)

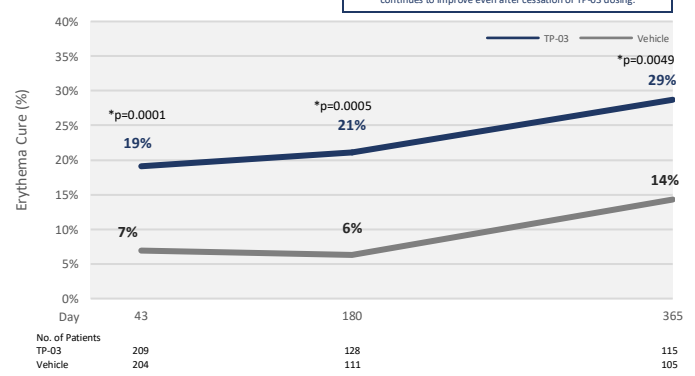


Clinically Meaningful Collarette Cure (≤10 collarettes)

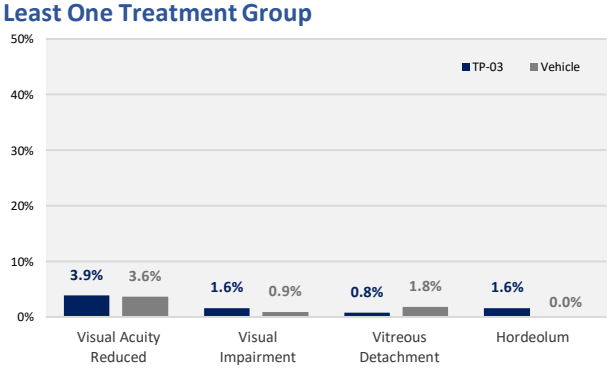


Erythema Cure (Grade 0)

Statistically significant difference between TP-03 and vehicle achieved at Days 180 and 365 after 43 days of BID dosing. Erythema continues to improve even after cessation of TP-03 dosing.



Ocular Adverse Events with Rate of >1% in at Least One Treatment Group



CONCLUSION

The results of Saturn-1 Extension showed that the collarette cure and erythema cure at days 180 and 356 remained significantly greater in the TP-03 group vs the control group. No serious adverse events were observed in this extended study.