

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 OR 15(d)  
of The Securities Exchange Act of 1934**

**Date of Report (date of earliest event reported): May 2, 2022**

**TARSUS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39614**  
(Commission  
File Number)

**81-4717861**  
(I.R.S. Employer  
Identification No.)

**15440 Laguna Canyon Road, Suite 160**  
**Irvine, CA 92618**  
(Address of principal executive offices, including Zip Code)

**Registrant's telephone number, including area code: (949) 409-9820**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	TARS	The Nasdaq Global Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01 Other Events.**

On May 2, 2022, Tarsus Pharmaceuticals, Inc. (the "Company") announced positive results of the Company's Saturn-2 trial. Saturn-2 is a Phase 3 randomized, controlled, double-masked trial evaluating the efficacy and safety of TP-03 in patients with Demodex blepharitis. A summary of the clinical results of the Saturn-2 pivotal Phase 3 trial is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Tarsus Pharmaceuticals, Inc. Saturn-2 Clinical Results Summary</a>
104	Cover Page Interactive Data File (embedded within XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 2, 2022

Tarsus Pharmaceuticals, Inc.

By: /s/ Leo M. Greenstein  
Leo M. Greenstein  
Chief Financial Officer  
*(Principal Financial Officer and Principal Accounting Officer)*

# Saturn-2 Phase 3 Topline Data



## TP-03 Met All Primary and Secondary Endpoints Again in Saturn-2, with a Complete Resolution of Demodex Blepharitis

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- **Efficacy:** Met all pre-specified primary and secondary endpoints

- ✓ Primary Endpoint: Complete **Collarette Cure**  $p < 0.0001$
- ✓ Secondary Endpoint: **Mite Eradication**  $p < 0.0001$
- ✓ Secondary Endpoint: **Erythema Cure**  $p < 0.0001$
- ✓ Secondary Endpoint: **Erythema/Collarette Composite Cure**  $p < 0.0001$

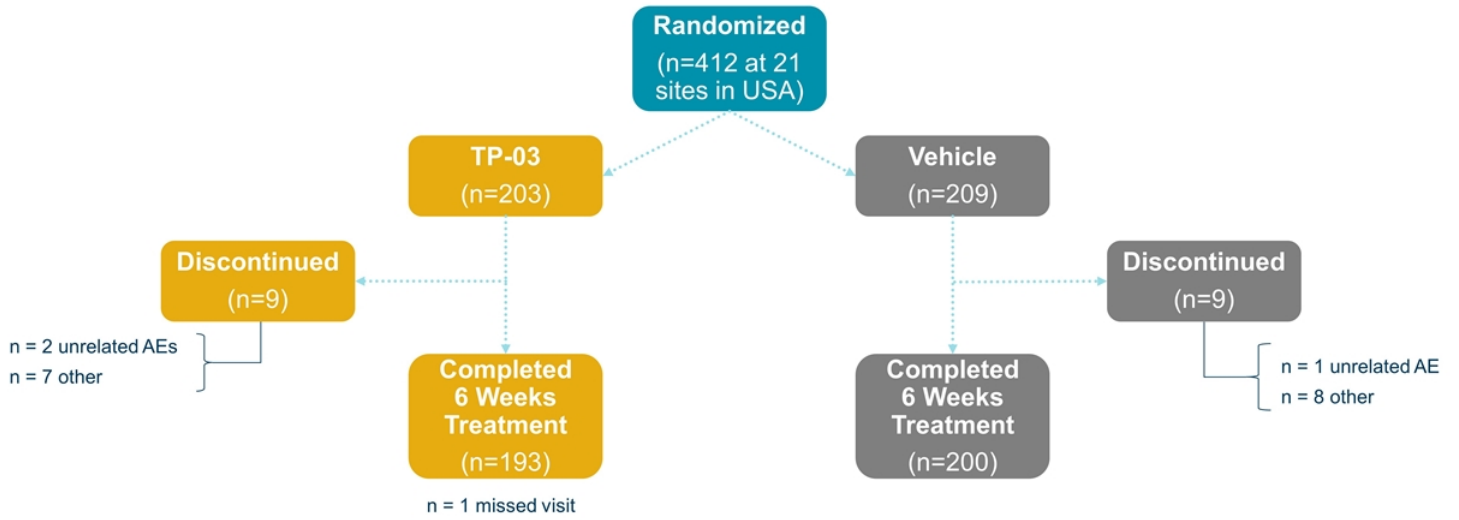
- **Safety:** Generally safe and well tolerated, similar to Saturn-1

- ✓ Low rates of TP-03 related AE's, vast majority were mild
- ✓ 91% of patients reported the drop to be neutral to very comfortable




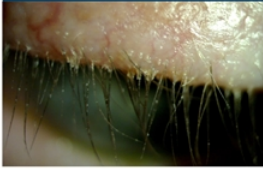

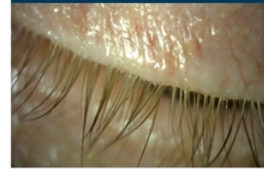

# Patient Enrollment and Follow-up

6 Week Treatment and Follow-up, Twice Daily Drop Without any Touching or Wiping of Lid Margin



# Collarette Grading Scale Used in Saturn-2

Non-linear Scale for Counting Collarettes Performed by Each Site Investigator

Grade 4	Average baseline Grade 3	Grade 2	Grade 1	Grade 0
				
<ul style="list-style-type: none"><li>• <b>&gt;2/3 of lashes</b> on lid with collarettes</li><li>• Approximately 150 collarettes/lid</li></ul>	<ul style="list-style-type: none"><li>• <b>Between 1/3-2/3 of lashes</b> on lid with collarettes</li><li>• Approximately 100 collarettes/lid</li></ul>	<ul style="list-style-type: none"><li>• <b>Between 10 collarettes to 1/3 of lashes</b> on lid with collarettes</li><li>• Approximately 50 collarettes/lid</li></ul>	<ul style="list-style-type: none"><li>• <b>3-10 collarettes</b> on the lashes</li></ul>	<ul style="list-style-type: none"><li>• <b>0-2 collarettes</b> on the lashes</li><li>• Cure of collarettes</li></ul>



Photos are images taken of patients in Saturn-1 with the corresponding collarette grade.  
4 | © Tarsus Pharmaceuticals 2022



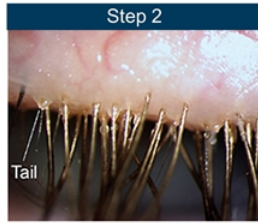
# Mite Density Determination Used in Saturn-2

## Trained Mite-counters (CRO) Used for Consistency Across Sites



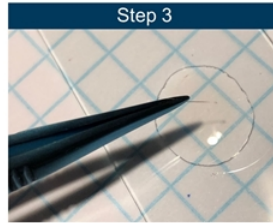
Step 1

- **Two or more lashes** from each of the upper and lower eyelids, one from each half of each lid, should be twirled with gentle tensioning for at least 10 seconds and removed using fine forceps



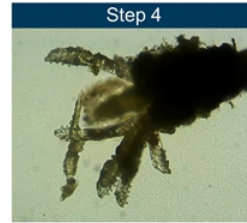
Step 2

- **Lashes with collarettes**, if present, should be selected
- Occasionally, tails of mites can be observed in slit lamp examination



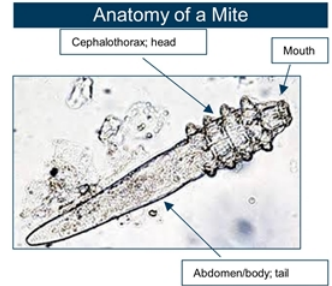
Step 3

- Lashes from each lid are placed on a separate glass slide resulting in **eight lashes on four slides**
- An artificial tear with an emulsifier (Refresh Optive® Advanced or Refresh Optive Mega 3®) should be applied prior to the placement of the lashes and then a coverslip is placed
- The sample is allowed to sit for approximately 15 minutes to allow the drop to penetrate the collarettes and let the mites disperse



Step 4

- Using a microscope, the number of *Demodex* observed and the number of lashes epilated are counted for each eye
- **Mite density** is determined by dividing the number of *Demodex* observed by the number of lashes epilated for each eye



Anatomy of a Mite

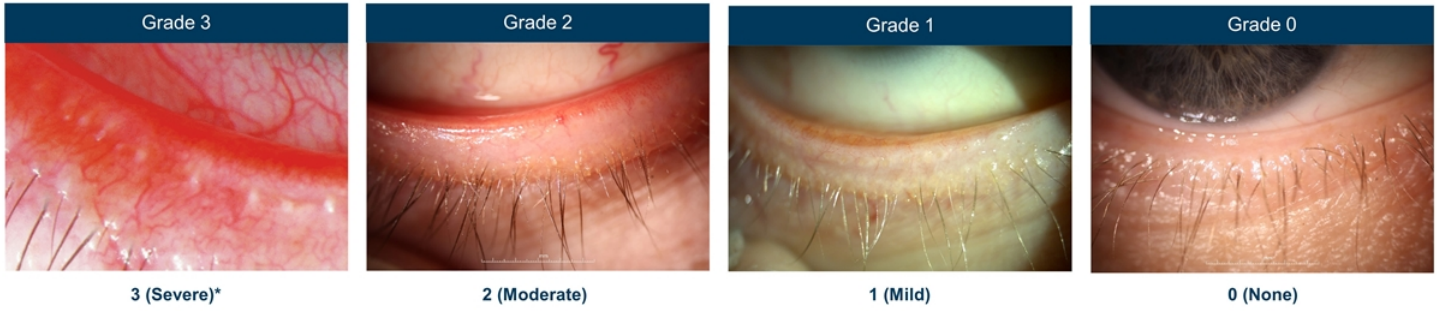




# Lid Margin Erythema (Redness) Scale Used in Saturn-2

Established and Validated Scale Used in Blepharitis Studies, Performed by Each Investigator

Average baseline 1.6



Hosseini K, Bourque LB, Hays RD. Development and evaluation of a measure of patient-reported symptoms of blepharitis. Health and Quality of Life Outcomes 2018;16:11 May 2018. Drug Design, Development and Therapy Volume 12:1269-1279  
\*Image reproduced with permission from Jiang et al. Efficacy of intra-meibomian gland injection of the anti-VEGF agent bevacizumab for the treatment of meibomian gland dysfunction with lid-margin vascularity. Drug Design, Development and Therapy 2018;12:1269-1279. © Dove Medical Press Limited. Grades 0, 1, and 2 images are from patients in Saturn-1.

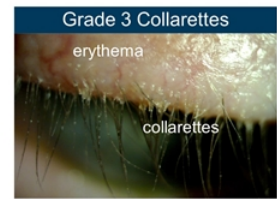
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# Saturn-2 Baseline Characteristics

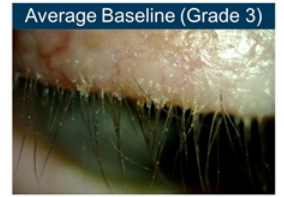
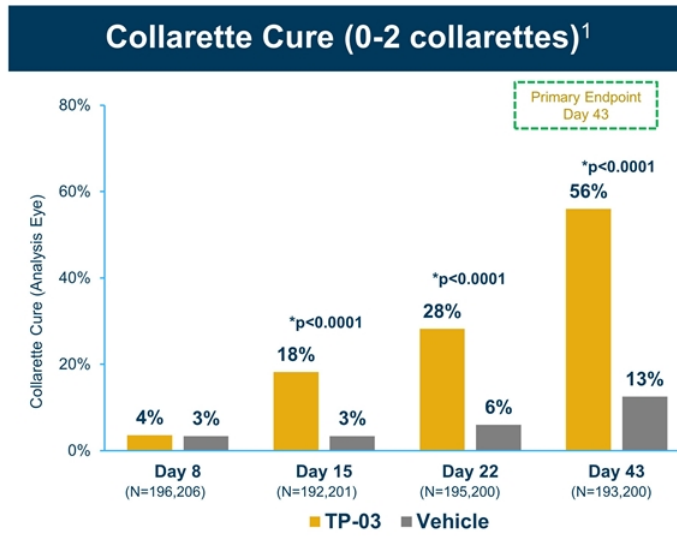
Similar to Saturn-1

	TP-03	Vehicle
<b>Patients</b>	203	209
<b>Age</b>	64	65
<b>Female %</b>	48	49
<b>Collarette Score</b>	2.9	3.0
<b>Mite Density</b>	3.2	3.4
<b>Erythema Score</b>	1.6	1.6



# Primary Endpoint of Complete Collarette Cure Achieved

Regulatory Endpoint of Complete Collarette Cure Observed by Week 2



<sup>1</sup> The primary efficacy endpoint was the proportion of patients achieving collarette cure (0-2 collarettes on the eyelid) as compared to the vehicle control, at day 43.  
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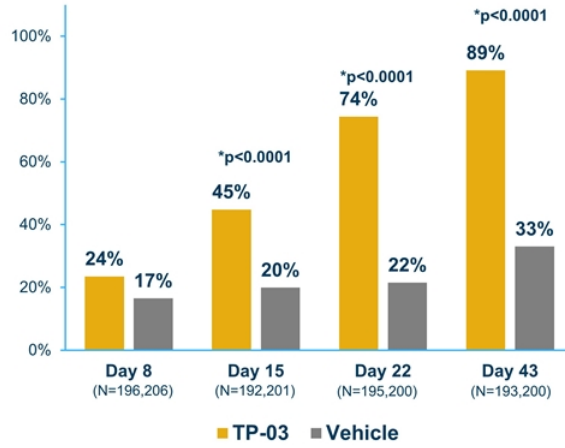


# Clinically Meaningful Collarette Cure Achieved

Clinically Meaningful Collarette Cure Observed by Week 2

Over 90% Avg. Reduction in Collarettes (Over 100 to 10 or Less per Lid)

## Grade 0 or 1 Collarettes



Average Baseline (Grade 3)



Grade 1



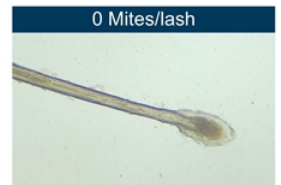
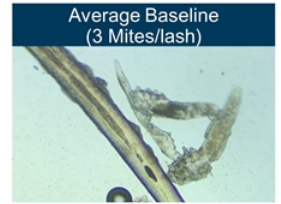
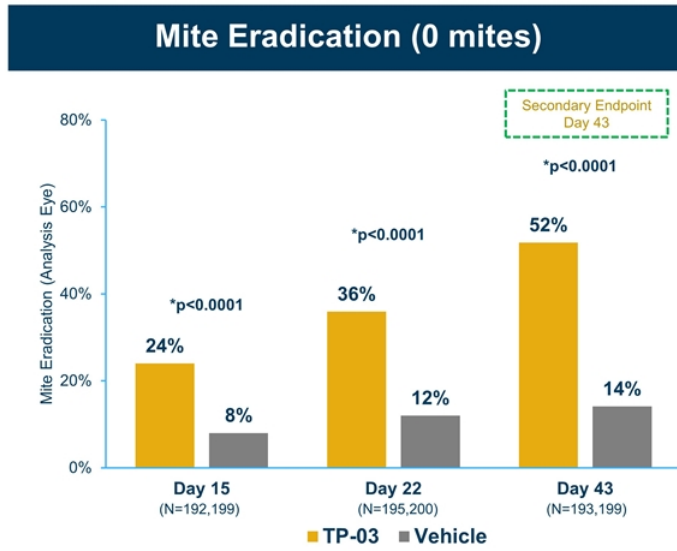
Grade 0



# Secondary Endpoint of Mite Eradication Achieved

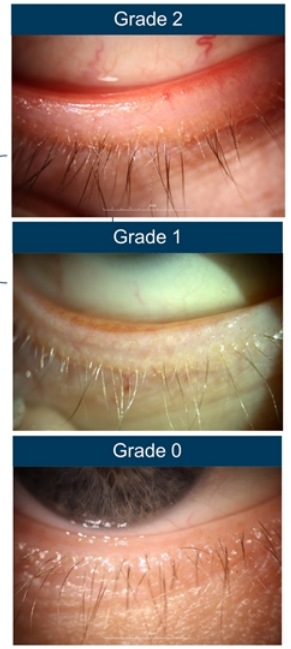
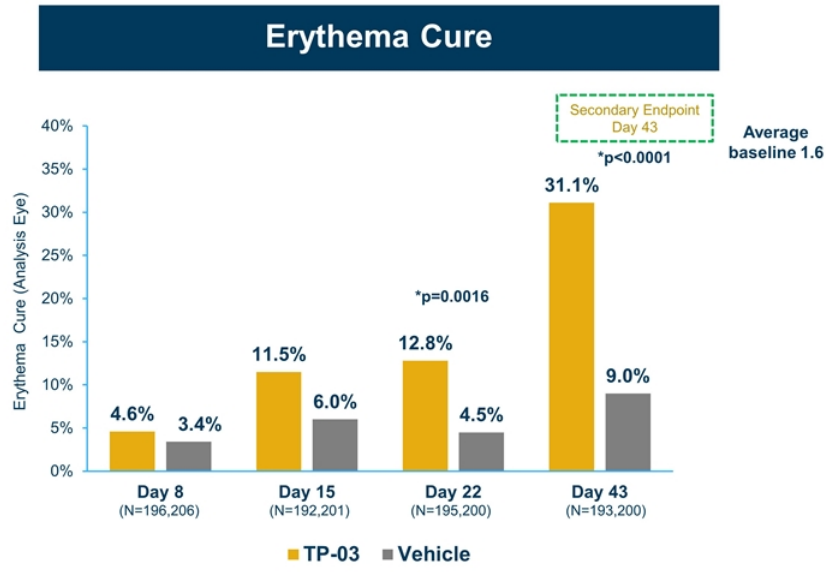
Complete Mite Eradication Observed by Week 2

Over 50% of Patients Experienced Complete Eradication at Week 6 (Secondary Endpoint)



# Secondary Endpoint of Erythema Cure Achieved

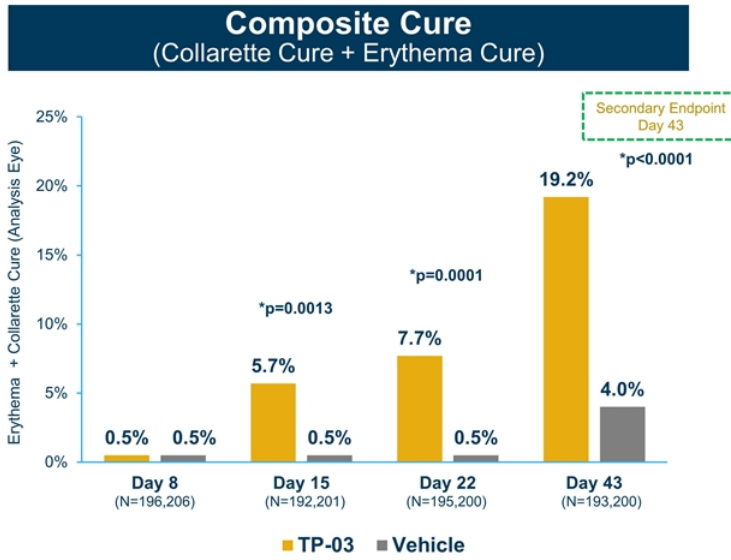
Elevated to Secondary Endpoint in Saturn-2  
Complete Erythema Cure Observed by Week 3



Ora Calibra® Scale

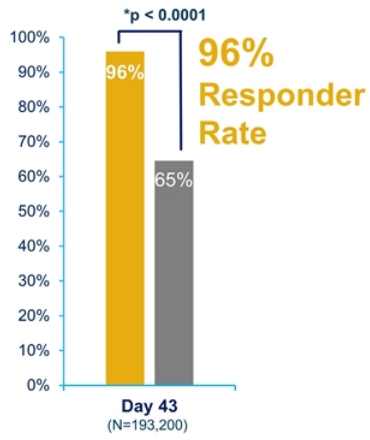
# Secondary Endpoint of Complete Composite Cure Achieved

Complete Composite Cure Observed by Week 2

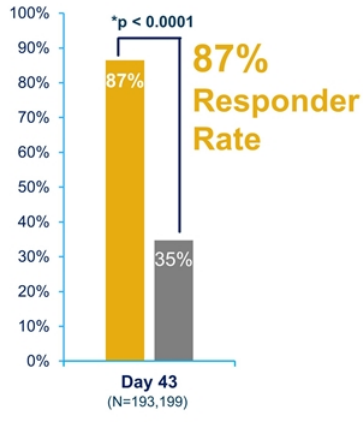


# Collarette, Mite & Erythema Improvement Responder Rates

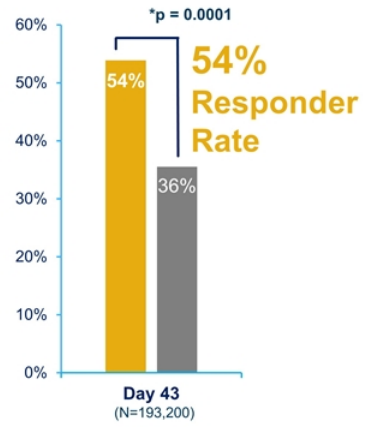
## ≥1 Grade Collarette Improvement



## Patients Achieving ≤ 0.5 Mites/Lash



## ≥1 Grade Erythema Improvement



TP-03 Vehicle





# Adverse Event Summary

Overall Low Rates of Ocular AEs

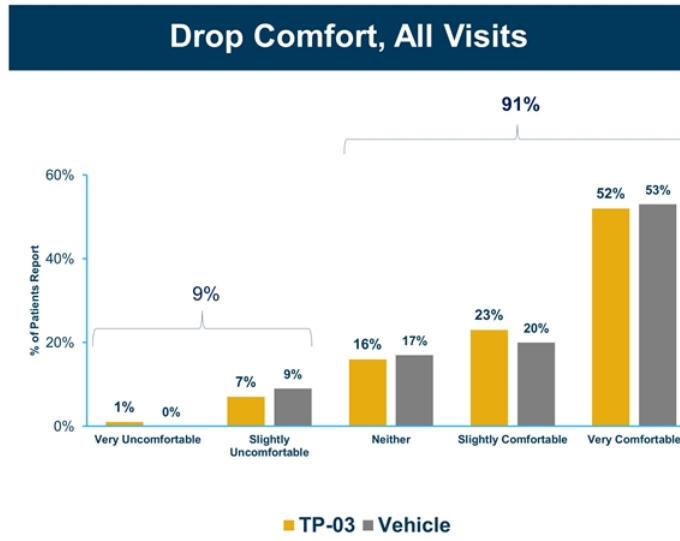
All AEs Were Mild or Moderate

Treatment related ocular AE rates $\geq$ 1%		
	TP-03 (n=203)	Vehicle (n=209)
Instillation site pain/burning/stinging	16 (7.9%)	14 (6.7%)
Visual acuity reduced	1 (0.5%)	3 (1.4%)
Dry eye	3 (1.5%)	1 (0.5%)
AE Severity	Two moderate All others mild	One moderate All others mild



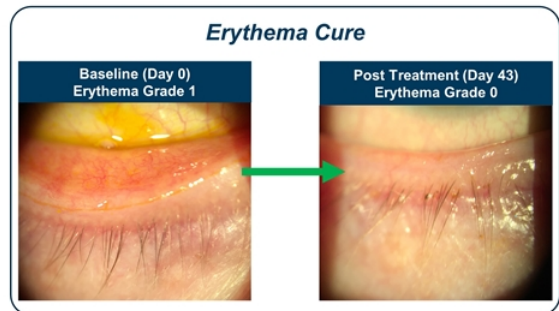
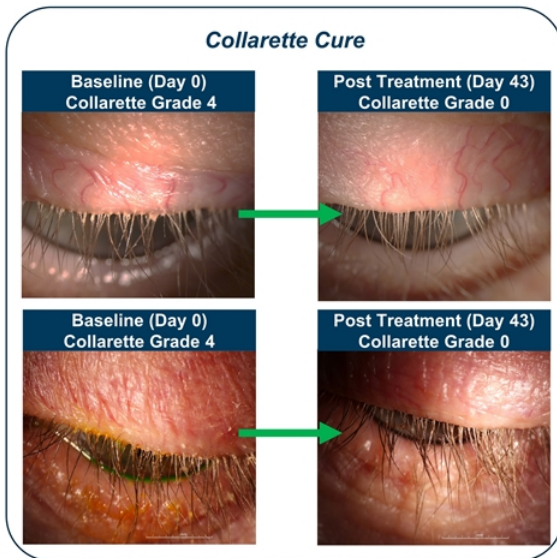
# Drop Comfort Summary

Over 90% Reported the Drop to be Neutral to Very Comfortable



# Significant Clinical Impact Seen After Treatment

Consistent Collarette Cure and Erythema Cure Rates Observed



Photos are images taken of patients in Saturn-2. Images demonstrate results which we believe are representative of favorable treatment with TP-03 for patients participating in the Saturn-2 trial. Other patients may experience different or less favorable results.

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## Saturn-2 Conclusions

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Saturn-2 Results Position TP-03 for Potential FDA Approval and Ultimate Commercial Success

- **56% of patients met primary endpoint of complete collarette cure**
- **Very high responder rate to TP-03**
  - 96% of patients improved at least one collarette grade, 89% achieved a clinically meaningful cure
- **Strong consistency across all endpoints compared with Saturn-1**
- **All primary and secondary endpoints met with high statistical significance**
- **Clinically and statistically significant effects seen within 2 weeks**
- **TP-03 was generally safe and well tolerated, similar to Saturn-1**



