

# Saturn-1 Investor Presentation

Pivotal Trial Topline Data and Corporate Update



# Legal Disclaimer

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This presentation contains forward-looking statements that involve risks and uncertainties. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current expectations about future events that we believe may affect our financial condition, results of operations, business strategy, and financial needs. All statements other than statements of historical facts contained in this presentation, including any statements regarding the ability of our clinical trials to demonstrate acceptable safety and efficacy of our product candidates, and other positive results; the timing, progress and results of clinical trials for our product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs; the timing, scope and likelihood of regulatory filings, NDA submissions and approvals; our ability to obtain marketing approvals of our product candidates and to meet existing or future regulatory standards or comply with post-approval requirements; our expectations regarding the potential advantages of our product candidates over existing therapies; the impact of COVID-19 on our business, clinical development programs and operations; our expectations with regard to our ability to develop additional product candidates or product candidates for other indications; our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives; our ability to develop, acquire and advance additional product candidates into, and successfully complete, clinical trials; the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; our expectations of the potential market opportunity and patient populations for our product candidates, including TP-03, TP-04, and TP-05 if approved for commercial use; the commercialization and market acceptance of our product candidates; and the implementation of our business model and strategic plans for our business and product candidates are forward-looking statements. The words “may,” “will,” “expect,” “anticipate,” “aim,” “estimate,” “intend,” “plan,” “believe,” “is/are likely to,” “potential,” “continue” and other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Important factors that could cause our actual results to differ materially are detailed from time to time in the reports we file with the Securities and Exchange Commission, copies of which are posted on our website and are available from us without charge. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Photos in this presentation relating specifically to the Saturn-1 trial will be explicitly denoted as such.

# Participants on Today's Call



## **Bobby Azamian, M.D., Ph.D., President & CEO, Co-Founder**

- Former CEO/CMO Metavention
- Extensive investment/entrepreneurial experience with Versant and Third Rock Ventures
- Medicine at Brigham, M.D., Harvard, Ph.D. Chemistry, Oxford



Metavention



## **Leo Greenstein, J.D., CPA, Chief Financial Officer**

- Former SVP, Finance & Corporate Controller of Spectrum Pharmaceuticals, Inc.
- 20+ years of finance leadership within publicly-traded companies
- Certified Public Accountant and Member of State Bar of California



## **Elizabeth Yeu, M.D., Chief Medical Advisor**

- Nationally recognized leader in Ophthalmology
- Cornea, Cataract, Refractive and Ocular surface specialist
- Future President American Society of Cataract and Refractive Surgeons (ASCRS)



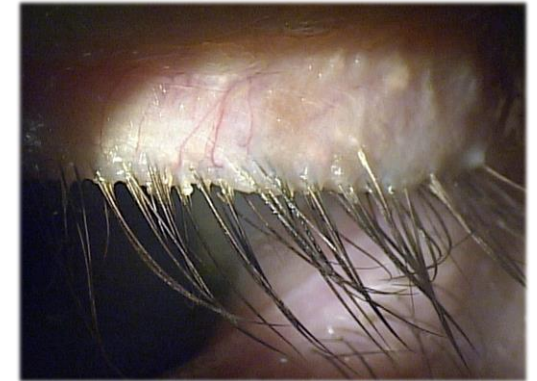
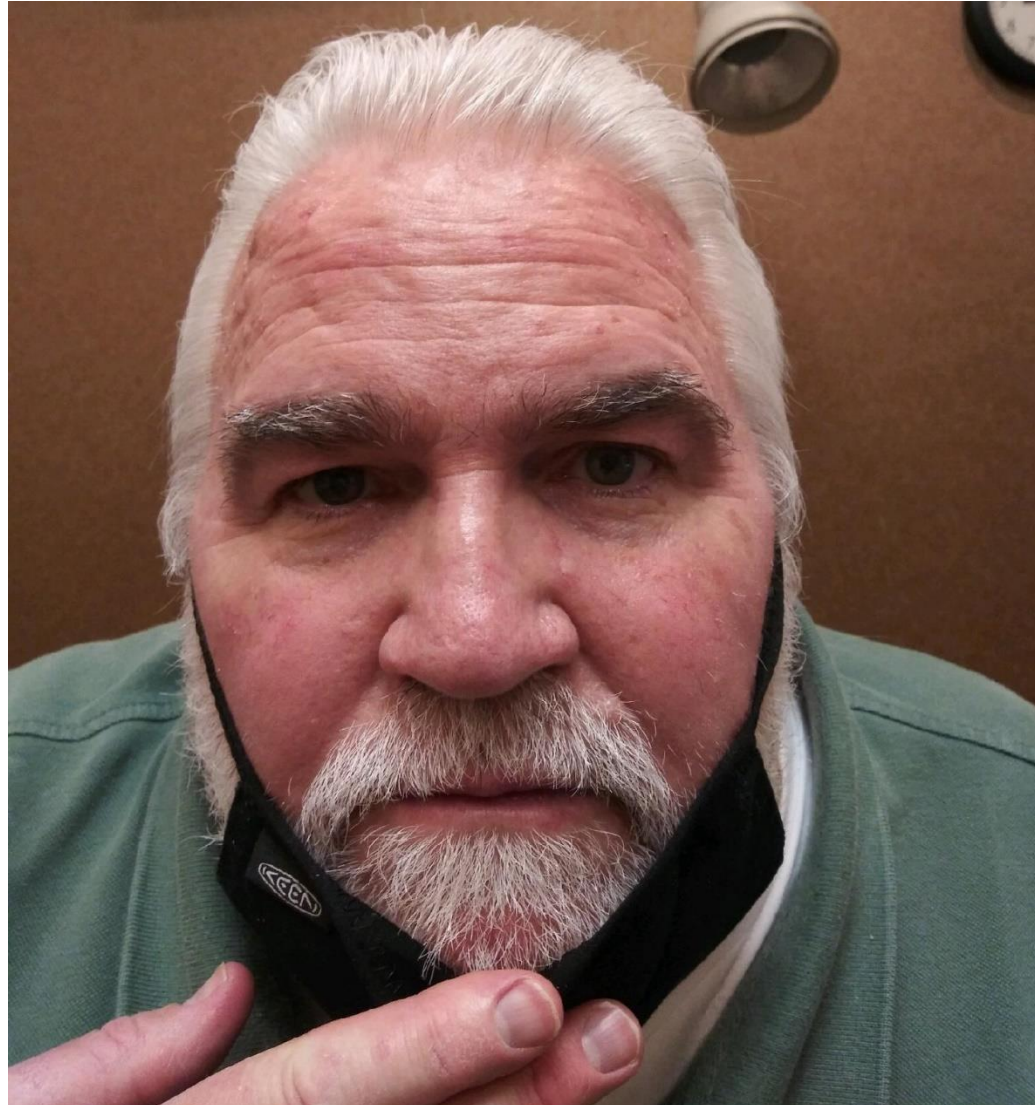
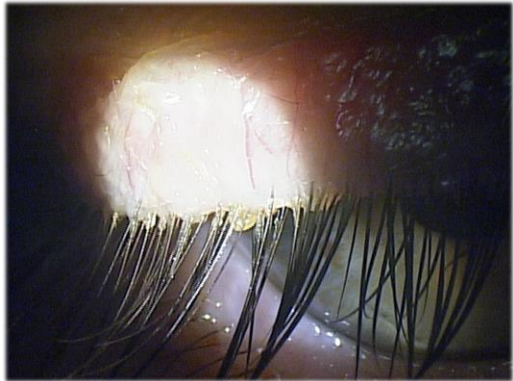
## **Aziz Mottiwala, MBA, Chief Commercial Officer**

- Former CCO Opiant, and Head of Commercial at Avanir
- Former VP Marketing, Allergan Eye Care, (Restasis®, Lumigan®)
- 20+ years of Commercial experience, with 10+ years in eye care



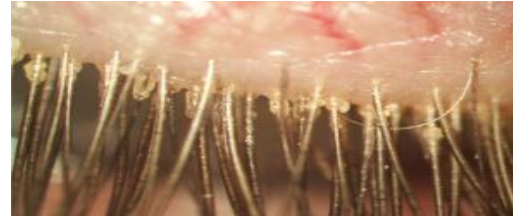
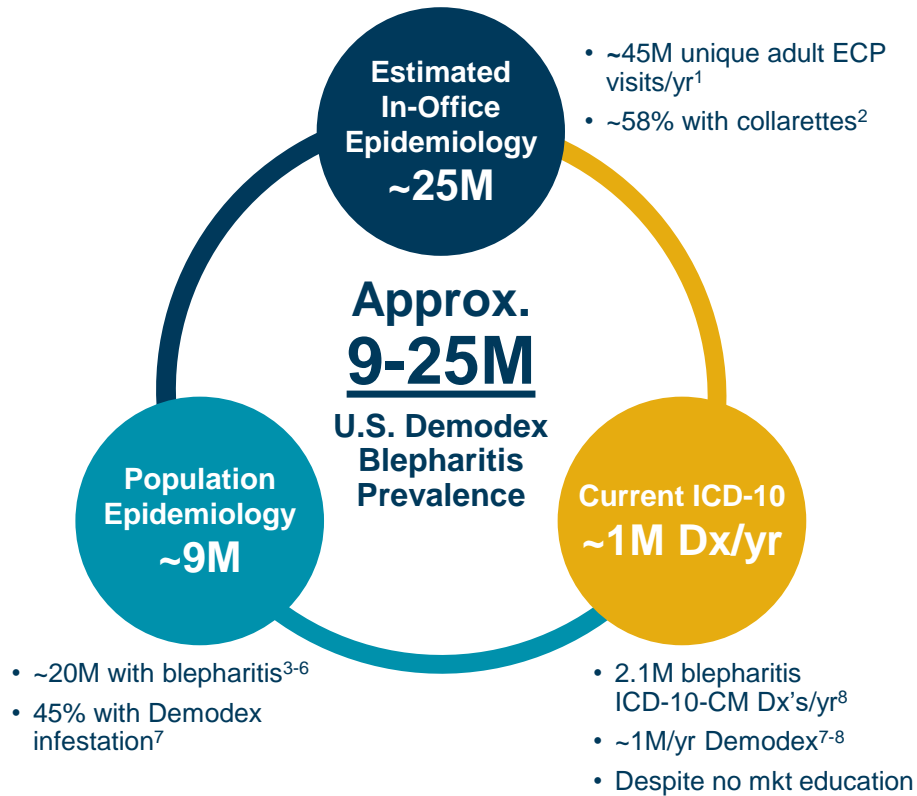
# Demodex Blepharitis

Example patient



# Blepharitis Is a Large and Underserved Market in Eye Care

## Epidemiology of Demodex Blepharitis



**Large Patient Population with Significant Disease Impact**

**Titan** (collarette clinic prevalence) and **Atlas** (disease impact) studies demonstrate high prevalence of disease and significant burden on patients

**Significant Head Start on Diagnosis**

2.1M ICD-10 **Blepharitis** Dx's/yr<sup>8</sup>

**Blepharitis Routinely Causes**

Eyelids to become red, irritated and itchy, with debris on the eyelashes.<sup>9</sup>

**Blepharitis Can Lead to**

Blurring of vision, missing or misdirected eyelashes, and inflammation of other eye tissue, particularly the cornea<sup>4</sup>

**Concomitant Dry Eye**

Significant overlap in **Dry Eye** patients. Demodex prevalent in ~69% of DE patients<sup>5</sup>

**Blepharitis and Surgery**

Important factor for maximizing surgical outcomes: 67% of **Cataract Patients** have Demodex blepharitis<sup>6</sup>

**Contact Lens Drop-out**

Studies have shown a direct correlation between Demodex blepharitis and **Contact Lens** intolerance<sup>10</sup>

**Prescription Treatment**

None; 81% of patients currently seeking treatment<sup>11</sup>



# Agenda

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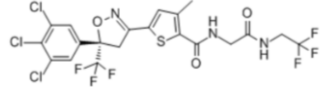
- **Saturn-1 topline data presentation**
- **Saturn-2 update**
- **Tarsus corporate update**
  - Corporate vision
  - TP-03 market opportunity
  - Pipeline progress update
  - Upcoming catalysts

# Saturn-1 Topline Data

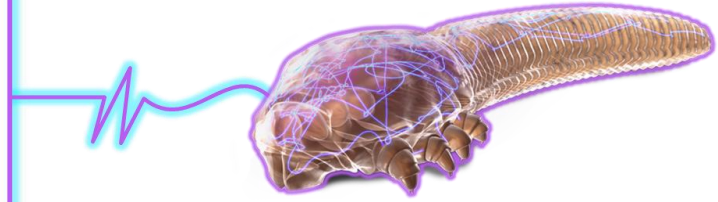









# TP-03 is a Novel Therapeutic Designed to Eradicate Demodex Mites and Treat Demodex Blepharitis

Lotilaner



- Potent non-competitive antagonist of insect and arachnid GABA-Cl channels
- Highly lipophilic molecule
- **Projected Orange Book Exclusivity to at least 2038**



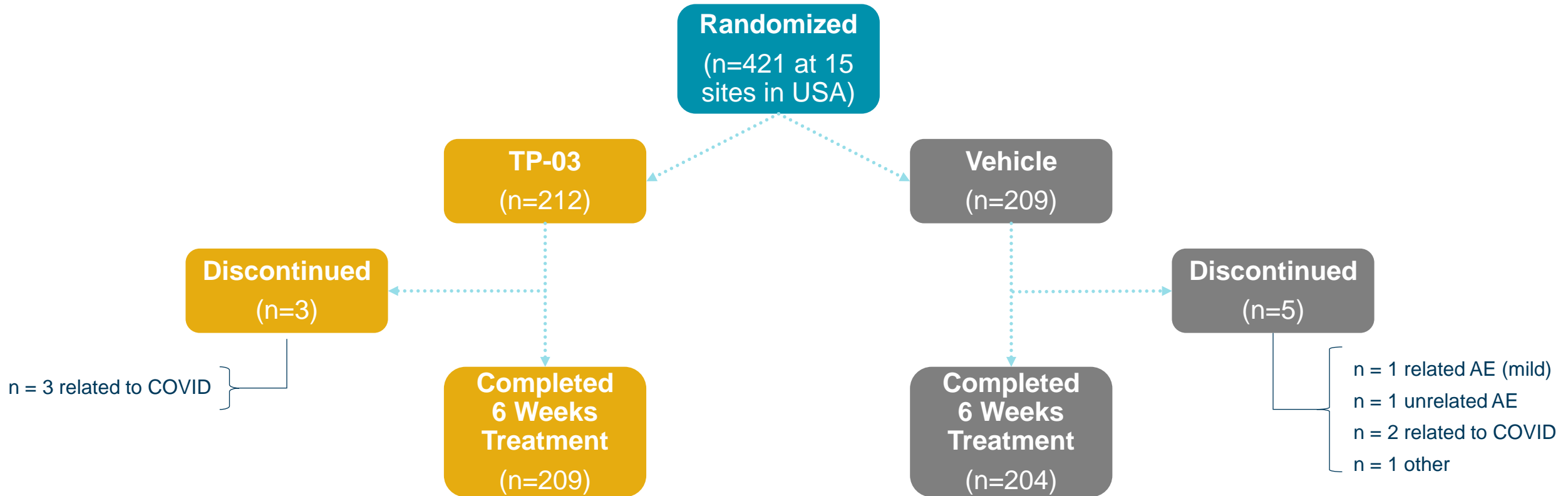
 <b>Product Form</b>	Multi-dose eye drop solution bottle, preserved
 <b>Targeted Use</b>	Treatment of Demodex blepharitis
 <b>MOA</b>	Paralysis and death of Demodex mites
 <b>Diagnosis</b>	Collarettes identified in standard eye examination
 <b>Dosing</b>	BID* for 6 weeks
 <b>Efficacy Goal</b>	1° collarette cure rate, 2° mite eradication, 2° redness + collarette cure rate
 <b>Safety Goal</b>	Well-tolerated safety profile





# Saturn-1 Patient Enrollment and Follow-up

6 Week Treatment and Follow-up, twice a day drop without any touching or wiping of lid margin



# Saturn-1: All Primary and Secondary Endpoints Met and Clinically Meaningful Effects Demonstrated with TP-03

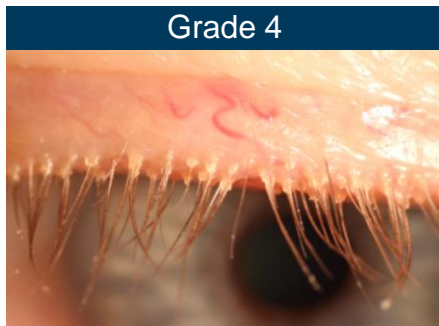
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- **Efficacy:** All pre-specified primary and secondary endpoints were met
  - ✓ Primary Endpoint: Complete Collarette Cure  $p < 0.0001$
  - ✓ Clinically Meaningful Collarette Cure (Grade 0 or 1)  $p < 0.0001$
  - ✓ Secondary Endpoint: Mite Eradication  $p < 0.0001$
  - ✓ Secondary Endpoint: Composite Lid Erythema and Collarette Complete Cure  $p < 0.0001$
  - ✓ Clinically Meaningful Composite Lid Erythema and Collarette Cure  $p < 0.0001$
  - ✓ Erythema Cure  $p = 0.0001$  and Erythema Response  $p = 0.0002$
  - ✓ Rapid Cures: Improvements Seen in 2 Weeks  $p \leq 0.0149$  in Primary and Secondary Endpoints
- **Safety:** TP-03 was well-tolerated, with safety profile similar to vehicle
  - ✓ All TP-03-related AE's were mild with no treatment related discontinuations
  - ✓ 92% of patients reported the drop to be neutral to very comfortable

# Collarette Grading Scale Used in Saturn-1

Non-linear scale for counting collarettes performed by each site investigator

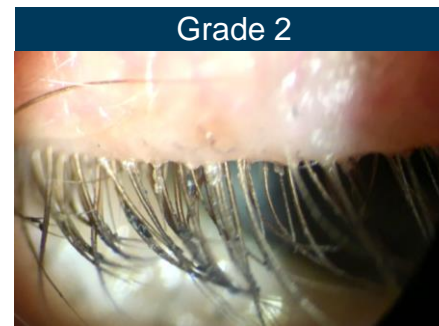
Average baseline



- **>2/3 of lashes** on lid with collarettes
- Approximately 150 collarettes/lid



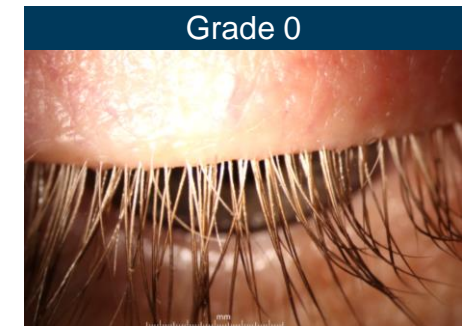
- **Between 1/3-2/3 of lashes** on lid with collarettes
- Approximately 100 collarettes/lid



- **Between 10 collarettes to 1/3 of lashes** on lid with collarettes
- Approximately 50 collarettes/lid



- **3-10 collarettes** on the lashes



- **0-2 collarettes** on the lashes
- Cure of collarettes

# Mite Density Determination Used in Saturn-1

Trained mite-counters (CRO) used for consistency across sites



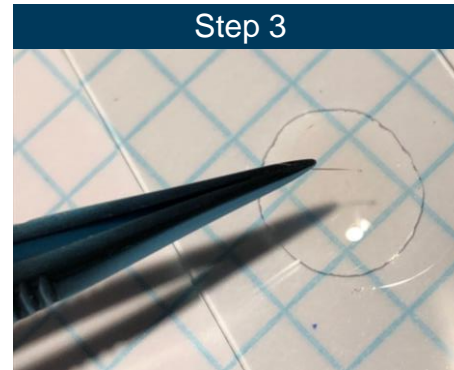
Step 1

- **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



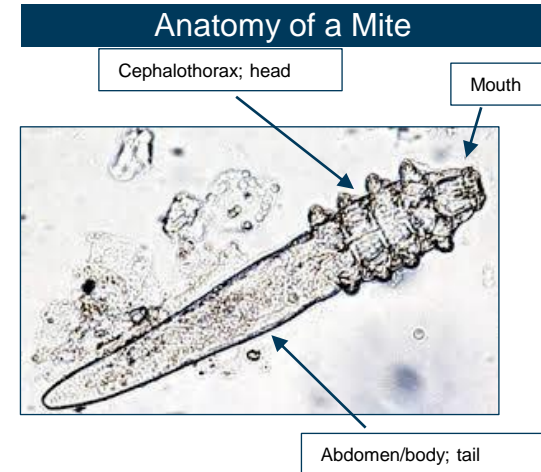
Step 3

- 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



# Lid Margin Erythema Scale Used in Saturn-1

Established and validated scale used in blepharitis studies, performed by each investigator

Average baseline 1.5



Grade 3

3 (Severe)\*



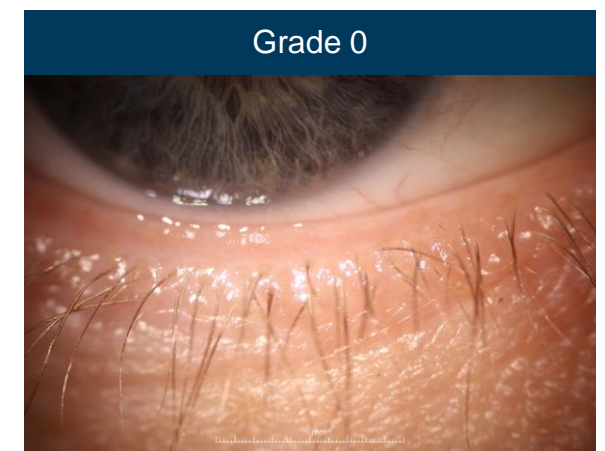
Grade 2

2 (Moderate)



Grade 1

1 (Mild)



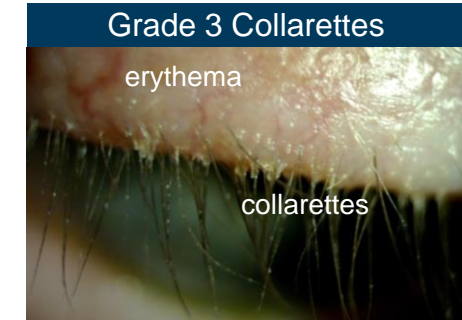
Grade 0

0 (None)



# Saturn-1 Baseline Characteristics

	TP-03	Vehicle
Age	66.1	67.8
Female %	58	56
Collarette Score	2.8	2.8
Mite Density	3.2	3.2
Erythema Score	1.5	1.5



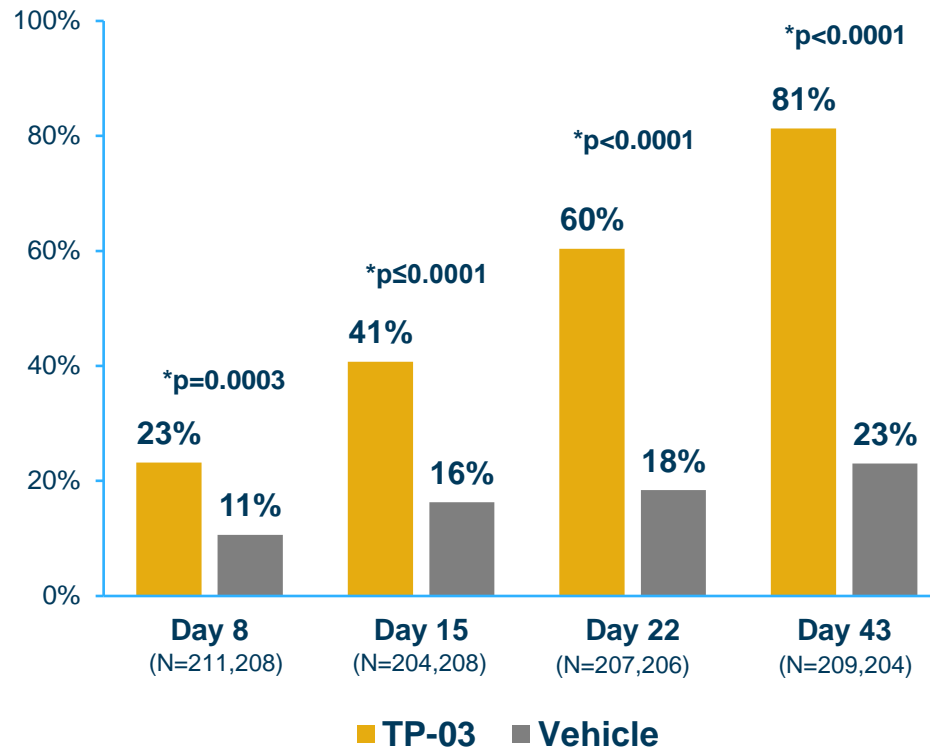


# Clinically Meaningful Collarette Cure

Clinically Meaningful Collarette Cure Observed by Week 1

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

## Grade 0 or 1 Collarettes



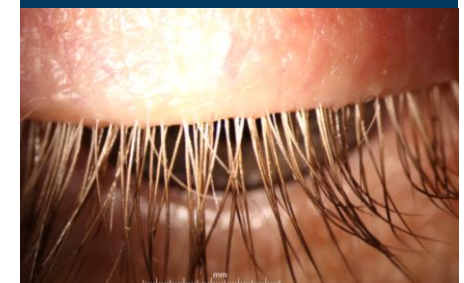
Average Baseline (Grade 3)



Grade 1

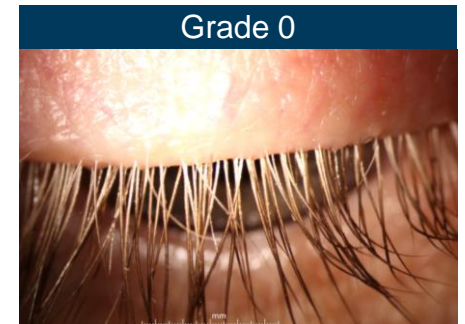
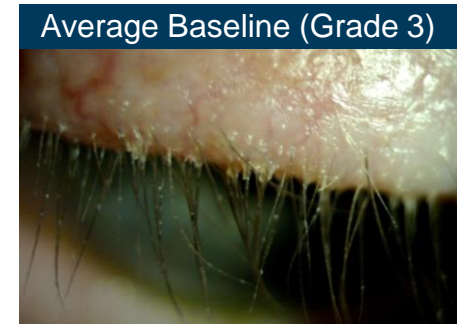
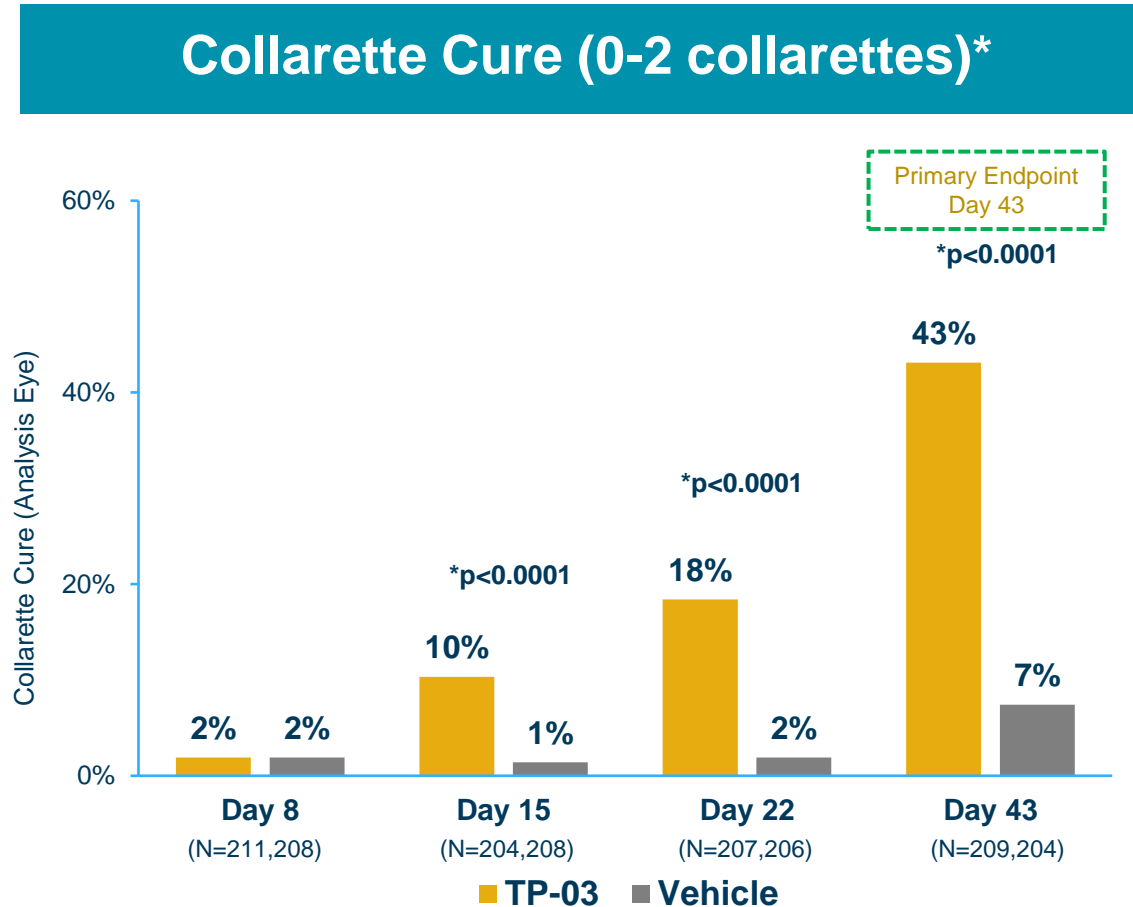


Grade 0



# Primary Endpoint of Complete Collarette Cure Achieved

Regulatory Endpoint of Complete Collarette Cure Observed by Week 2



\* 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.

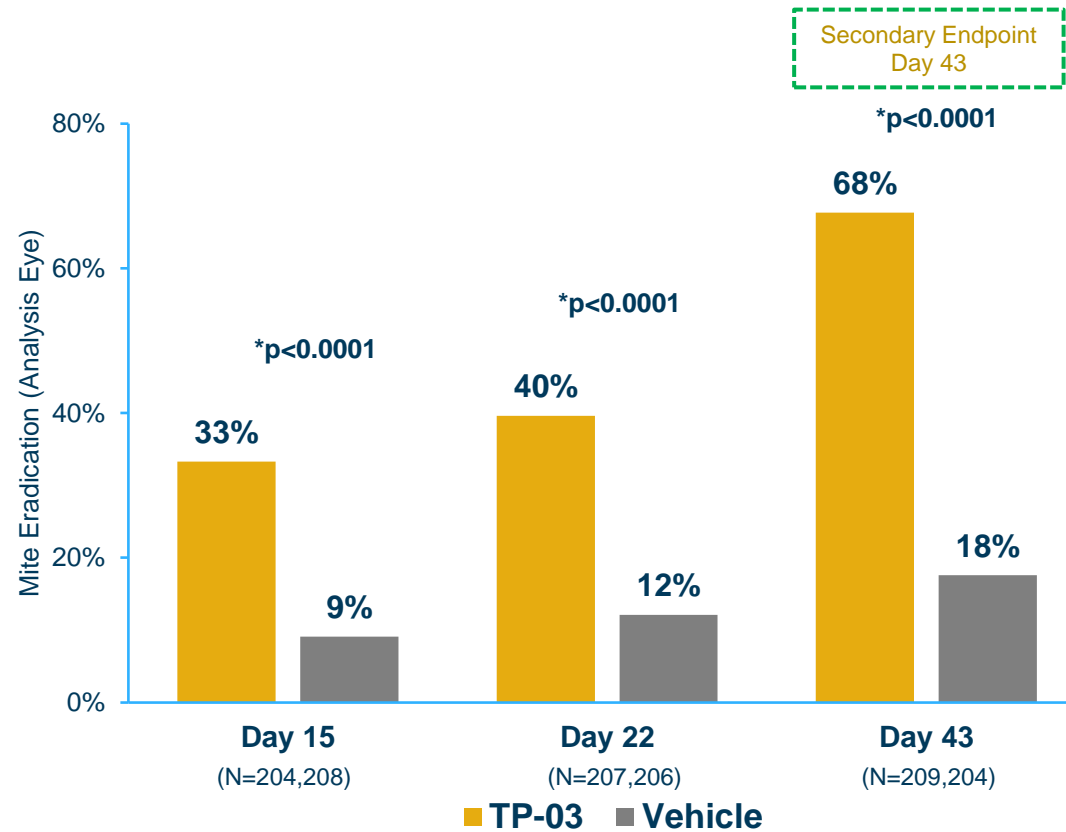
Photos are images taken of patients in Saturn-1 with the corresponding collarette grade.

# Secondary Endpoint of Mite Eradication Rate Achieved

Complete Mite Eradication Observed by Week 2

68% of Patients Experienced Complete Eradication at Week 6 (Secondary Endpoint)

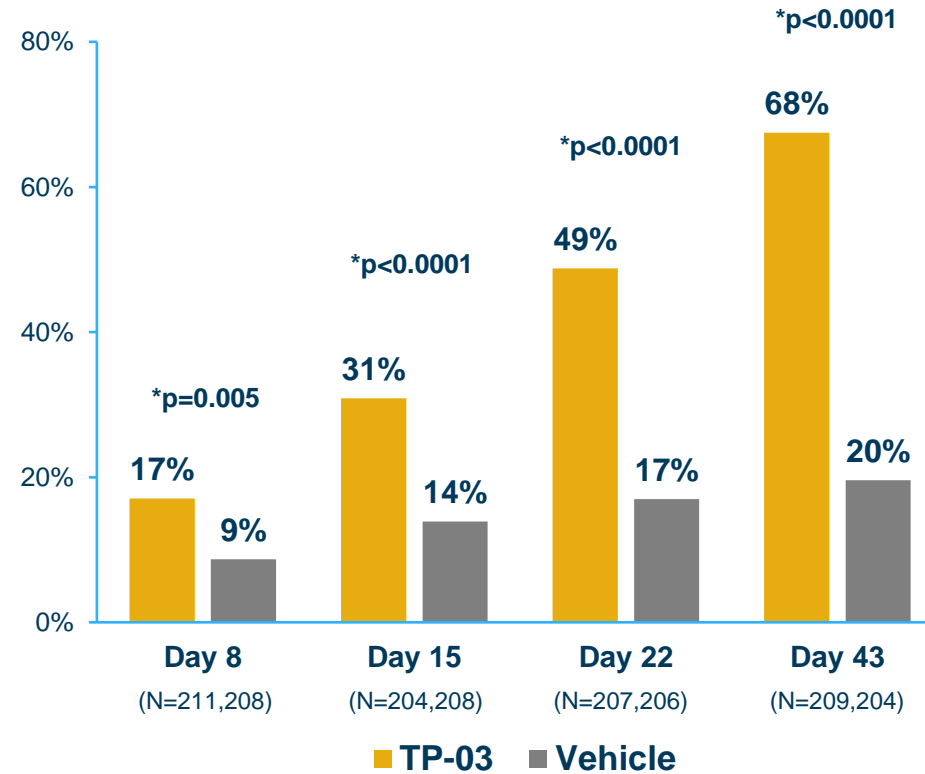
## Mite Eradication (0 mites)



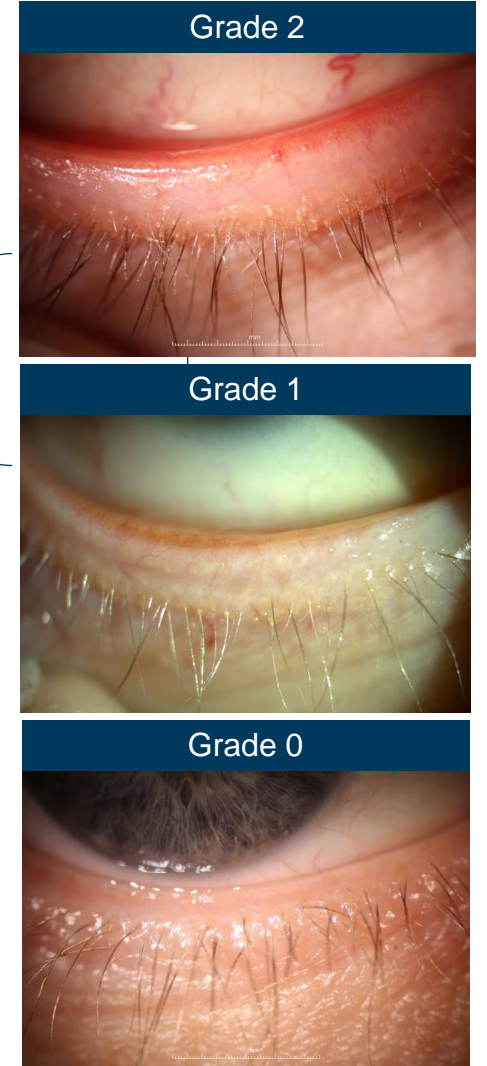
# Clinically Meaningful Composite Cure

Clinically Meaningful Composite Cure Improvements Observed by Week 2  
68% of Patients Experienced a Grade 0 or 1 Collarette and Erythema Score

## Grade 0 or 1 Collarette and Erythema Score

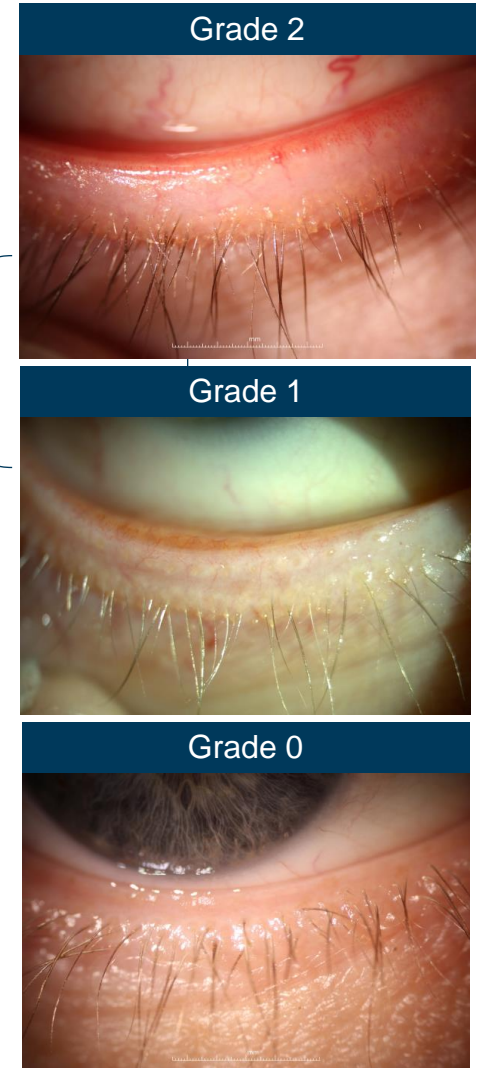
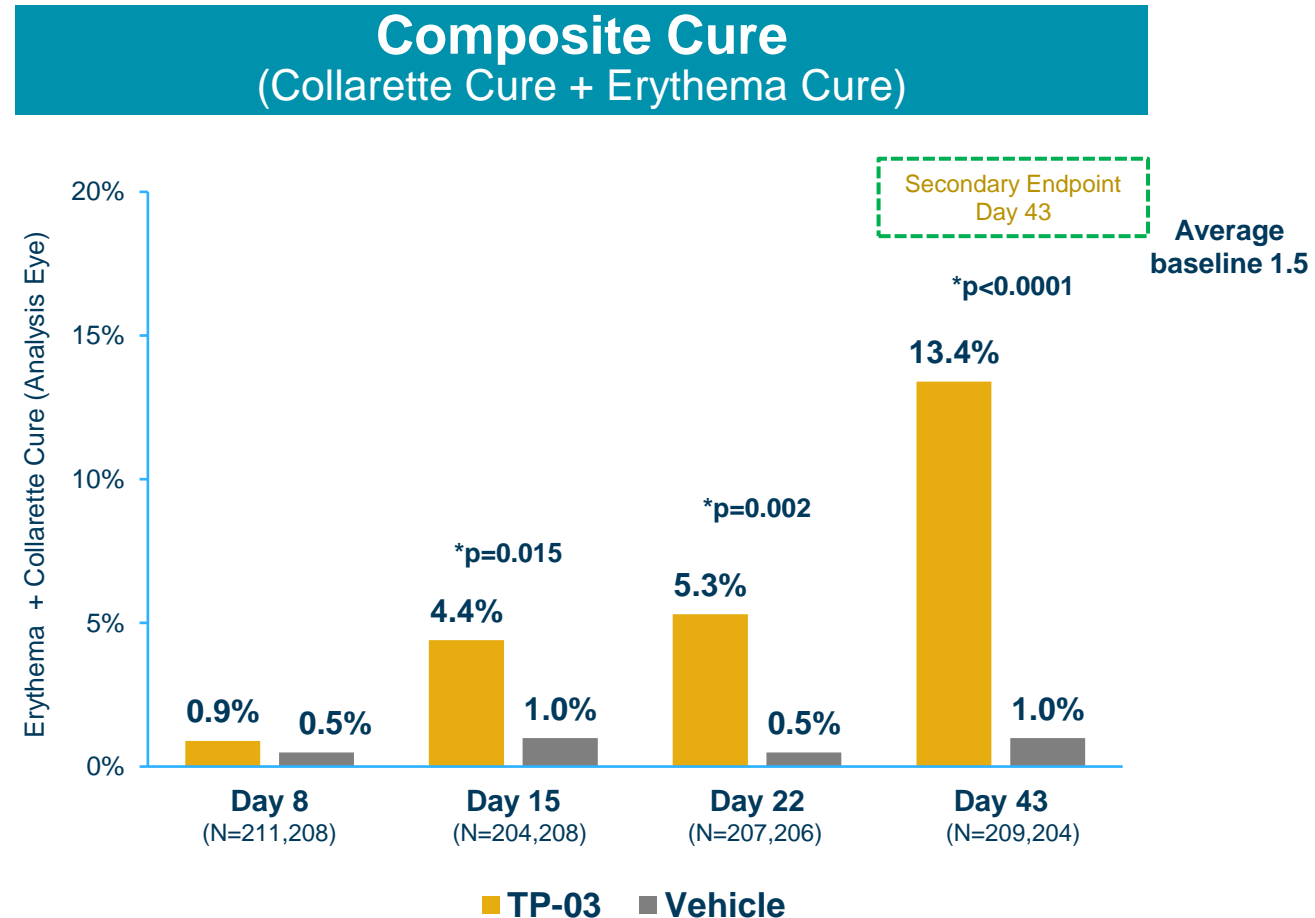


Average  
baseline 1.5



# Secondary Endpoint of Complete Composite Cure Achieved

Endpoint of Complete Composite Cure Observed by Week 2

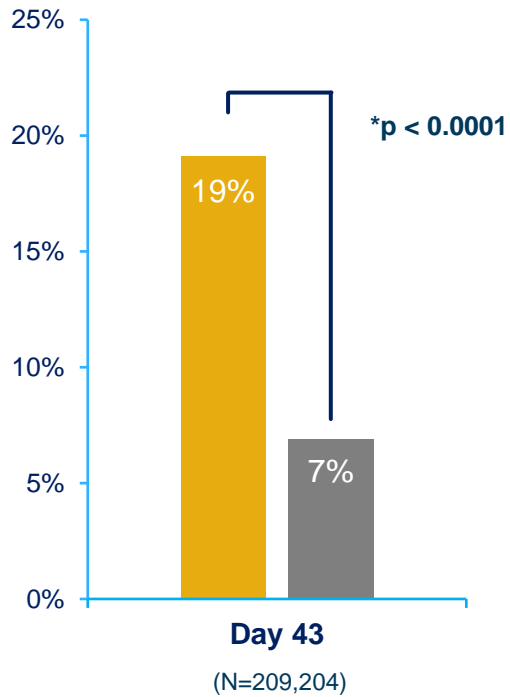


# Erythema Cure and Response

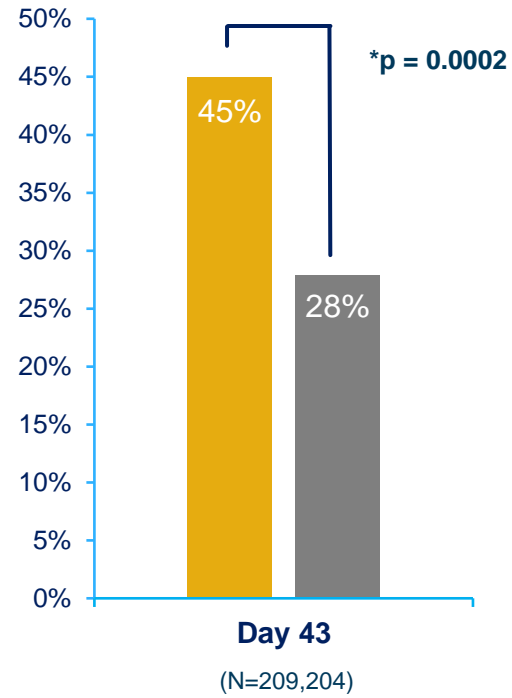
19% of Patients Experienced Complete Erythema Cure at Day 43

45% of Patients Experienced Erythema Improvement at Day 43

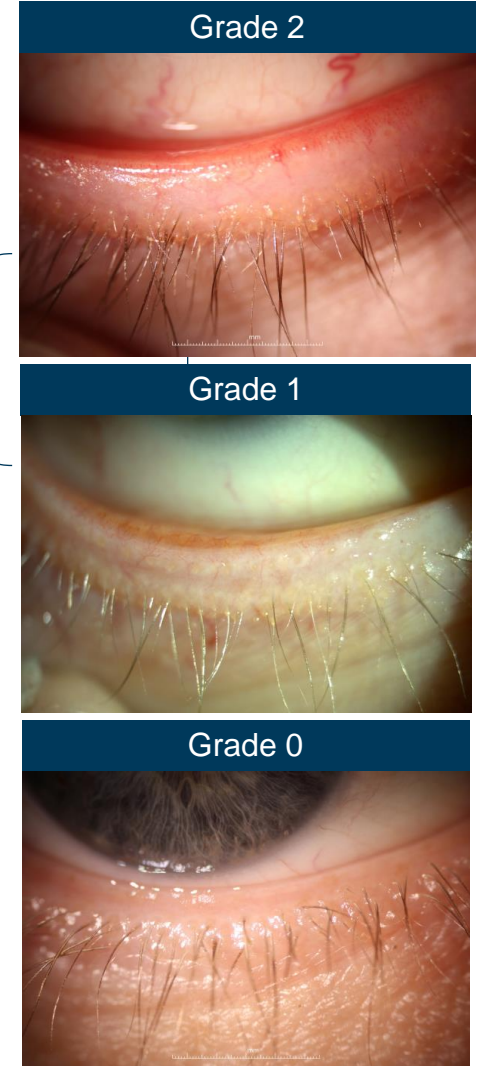
## Grade 0 Erythema



## 1 Grade or More Erythema Improvement



Average  
baseline 1.5





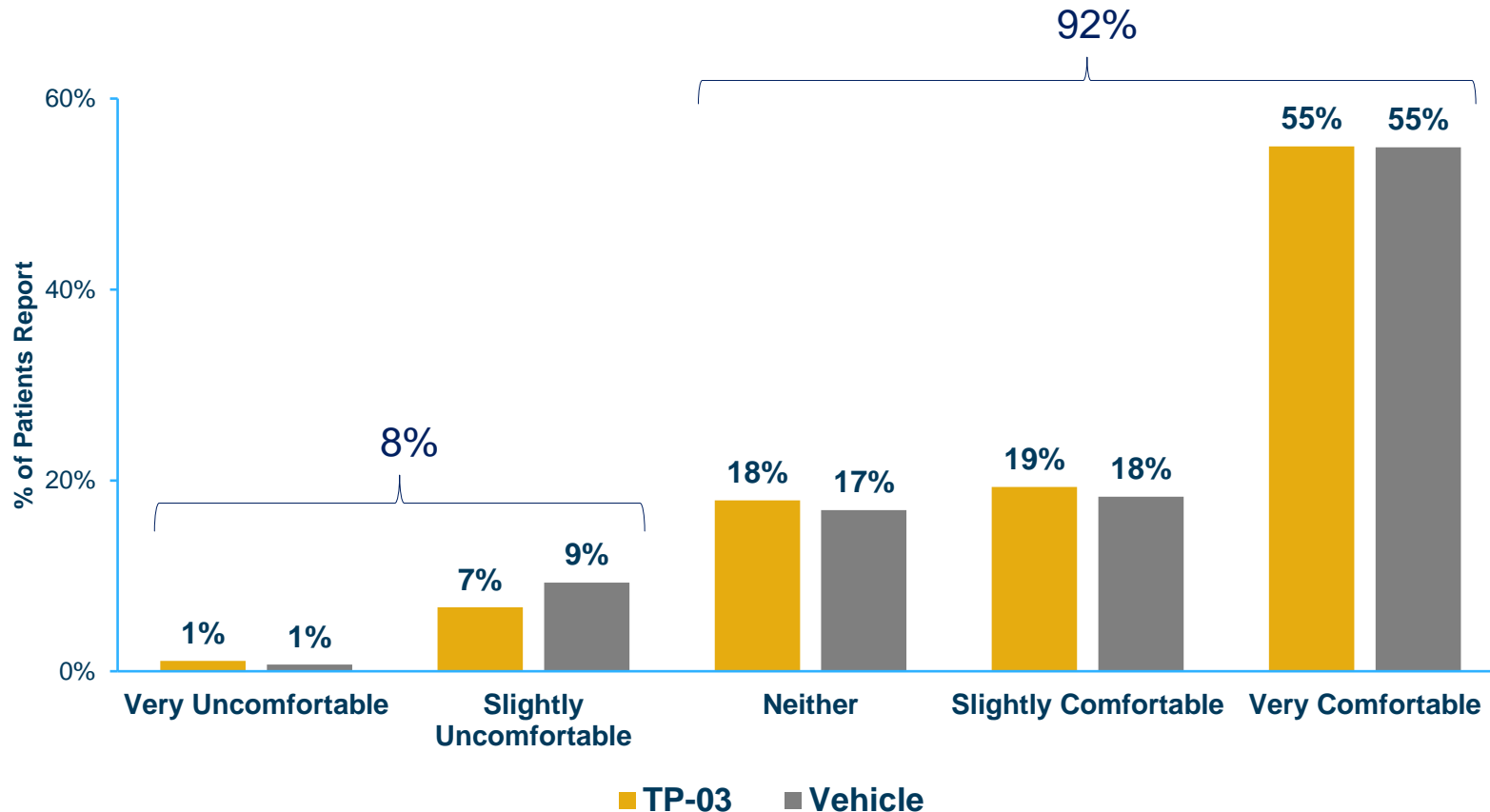
# Adverse Event Summary

- **Treatment related ocular AEs occurring at rate of  $\geq 1\%$  in active group**
  - Summary of Adverse Events occurring at any time during trial

	<b>TP-03 (n=212)</b>	<b>Vehicle (n=209)</b>
Instillation site pain/burning/stinging	25 (11.8%)	16 (7.7%)
Instillation site pruritis	3 (1.4%)	7 (3.3%)
Visual acuity reduced	3 (1.4%)	5 (2.4%)
Eye pain	3 (1.4%)	2 (1.0%)
Eye discharge	3 (1.4%)	1 (0.5%)
AE Severity	All Mild	One moderate AE All other AEs mild

# TP-03 Was Well Tolerated With 92% of Patients Reporting TP-03 to Be Neutral to Very Comfortable

## Drop Comfort, All Visits



# Improvements Seen Post Treatment Have Significant Clinical Impact

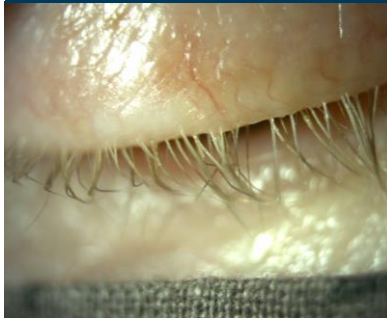
Cure rates and clinically meaningful effects validate the opportunity to benefit a large proportion of patients

## Complete Collarette Cure

Baseline (Day 0)  
Grade 4



Post Treatment (Day 43)  
Grade 0



## Clinically Meaningful Collarette Cure

Baseline (Day 0)  
Grade 4



Post Treatment (Day 43)  
Grade 1



Baseline (Day 0)  
Grade 2

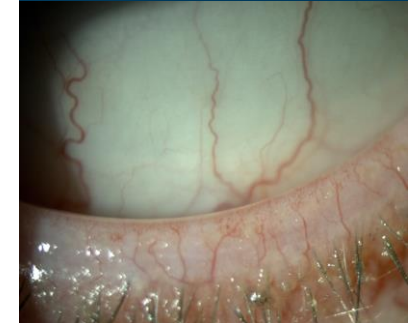


Post Treatment (Day 43)  
Grade 1



## Erythema Response

Baseline (Day 0)  
Erythema Grade 2



Post Treatment (Day 43)  
Erythema Grade 1



# Conclusions

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Saturn-1 results demonstrate a potentially powerful treatment for Demodex Blepharitis

- All primary and secondary endpoints met
- Clinically meaningful cures seen in 81% of patients
- All endpoints met with high statistical significance
- Erythema cure and improvements demonstrated
- Effects seen within 2 weeks across endpoints
- Positive safety profile
- Well tolerated

# Saturn-2 Update



# Saturn-2 Phase 3 Trial Design and Status

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- Trial initiated in May 2021
- Substantively similar trial design to Saturn-1
- Expect top-line data to read out in 1Q 2022



# Tarsus Vision & Corporate Update



## Our Vision

To become a **leading eye care pharmaceutical company** dedicated to meeting **patient needs** through **boundless therapeutic ingenuity.**

# Major Accomplishments Since IPO That Have Advanced Our Growth Strategy

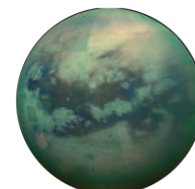
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Positive Saturn-1  
Topline Data



Saturn-2  
Enrolling



Titan Collarette  
Prevalence Study



Atlas Disease  
Impact Study



LianBio  
Partnership



TP-05 IND  
Accepted



Callisto TP-05  
Phase 1 Trial  
Initiated



Expanding Board with  
Biopharma Leadership

Wendy Yarno

# Titan Study Confirms Collarette Prevalence in ECP Clinic Patients and Key Patient Segments

## Study Overview

IRB-APPROVED  
RETROSPECTIVE  
CHART REVIEW

Examined presence of collarettes and other characteristics

LARGE-SCALE  
ALL-COMERS  
(1,032 patients)

Consecutive patients with a wide variety of reasons for visit

DIVERSE ANTERIOR  
SEGMENT  
CLINICS

Geographically diverse (7 US sites) including both MD and OD clinics

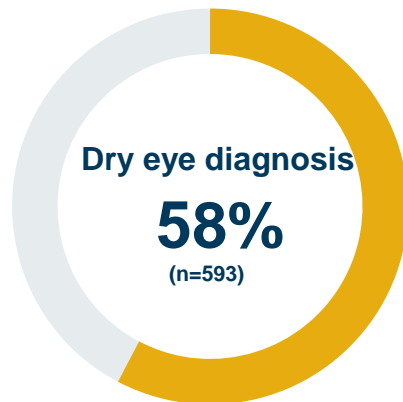
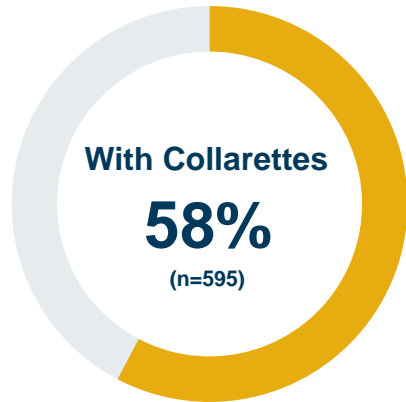
# 25M

## U.S. Demodex Blepharitis Patients

45M Unique Adults visiting an ECP per year; 58% of patients with collarettes

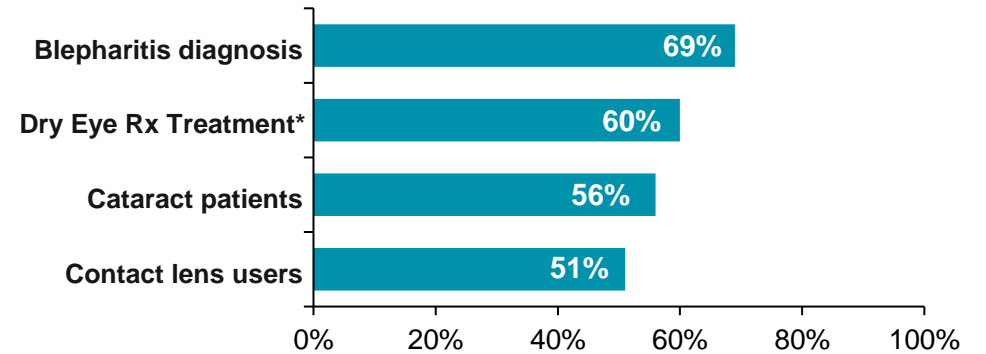
## Key Findings

### % of Overall Population



### Key Patient Groups

% with collarettes within each group



\* 22% of all study patients on Dry Eye Rx treatment

Additional Study at ARVO 2021 by Teo, Jacobson, Rosenberg showed (n=199):  
55% prevalence of Mites,  
62% overlap of Blepharitis  
68% overlap with Dry Eye

# Atlas Study Reveals Symptomatic and Psychosocial Burden of Demodex Blepharitis: 80% Report Negative Impact on Daily Life

- Data presented at ARVO 2021
- Multicenter, observational study of patients pre-screened for the Saturn-1 pivotal trial
- Evaluated the clinical and patient reported impact of *Demodex* blepharitis (interim analysis of 311 patients)
  - Presence of *Demodex* mites (at least 1 mite per lash)
  - Presence of collarettes (> 10, upper lid)
  - At least mild erythema

**51%**

Experienced signs and symptoms > 4 yrs

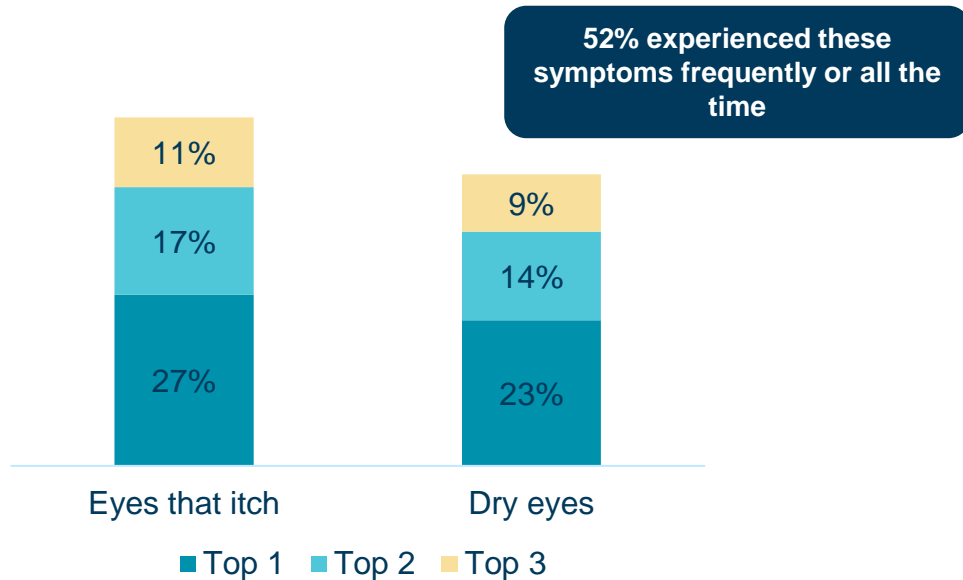
**58%**

Never diagnosed with blepharitis

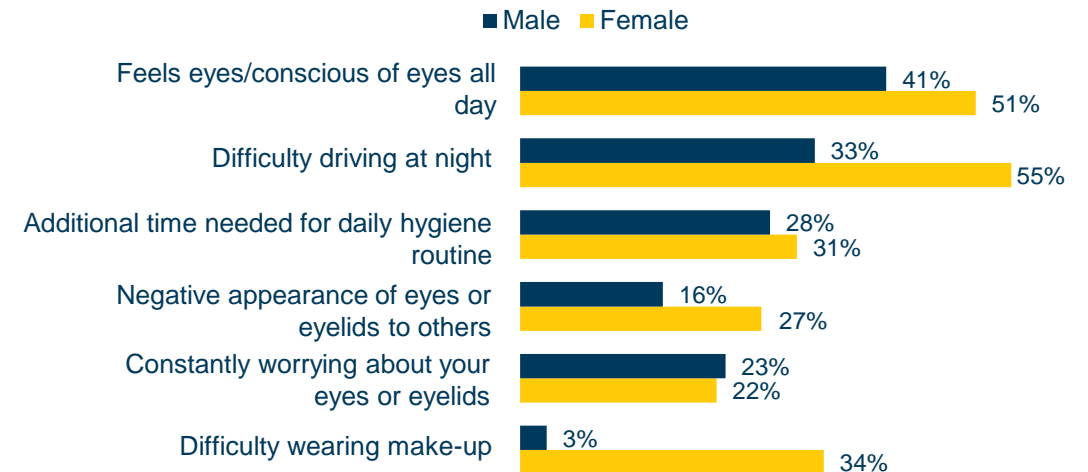
**33%**

Made at least 2, and sometimes more than 6, visits to a doctor for this condition

## Most Bothersome Symptoms



## Functional and Psychosocial Impact

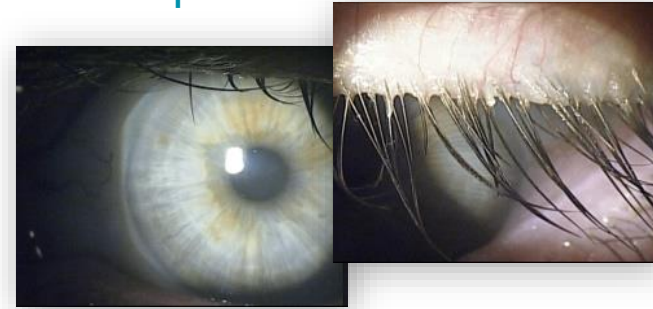


# Commercial strategy will be focused on unique and innovative approaches to market education and patient engagement

Positive disruption of existing norms will be at the core of our commercial plan

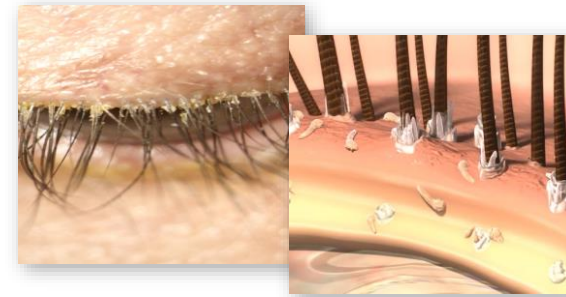
## Elevate eyelid health as a foundation of ocular wellness

- Educate on the importance, prevalence and impact of Demodex blepharitis, and how disease management can be part of the overall practice routine
- Build a strong scientific platform through KOL engagement, evidence generation, and data dissemination
- Establish key patient segments: Diagnosed Blepharitis, Cataracts, Dry Eye, Contact Lens Intolerance



## Transcend the annual visit cycle by leveraging compelling disease visuals and new technologies to drive patients into the ECP office

- Drive patients to seek optimal lid health outside the routine exam or contact lens refill
- Leverage social and other visual media to tell a motivating, visual disease story
- Explore telemedicine as a conduit to accelerate patient action and diagnosis



## Offer a cure with no barriers to facilitate market building through a unique patient experience














- Rapid, complete, and durable cure without hassle or frustration
- Couple broad reimbursement strategy with streamlined patient resources, discounts, and fulfillment
- Ensure patient touchpoints drive successful outcomes, initially, and for retreatment





# Pipeline with Different Formulations of Novel API

Current status and anticipated clinical trial events in our programs in the next 12 months

Candidate	Indication	Formulation	Preclinical	Phase 1	Phase 2	Phase 3	Status and Anticipated Future Milestones*	Worldwide Rights	
TP-03	Demodex blepharitis (DB)	 (Eye drop)						2021: Saturn-1 trial met primary and secondary endpoints; Saturn-2 Phase 3 trial initiated in May Q1 2022: Saturn-2 top-line data 2022: NDA filing	
	Meibomian Gland Disease (MGD)							Q4 2021: Initiate Phase 2a proof of concept**	
	Demodex blepharitis (Preservative-Free)		<i>Preservative-free formulation to be tested after NDA submission</i>					Bioequivalence studies (US)***	 (Greater China Rights)
	Demodex blepharitis and MGD in China							2021: Initiate pre-clinical work in China for DB and MGD 2022: Initiate Phase 3 DB trial in China*	
TP-04	Rosacea	 (Topical)						Q4 2021: Initiate Phase 1/2 trial †	
TP-05	Lyme Disease	 (Oral)						2021: IND Accepted Callisto Phase 1 trial initiated in June †† 1H 2022: Callisto Phase 1 trial completion	
	Malaria							2021: Callisto Phase 1 trial initiated in June †† 1H 2022: Callisto Phase 1 trial completion	

\* Anticipated milestones are subject to the impact of the ongoing COVID-19 pandemic on our business and those of our partners.

\*\* We intend to rely on preclinical studies and clinical safety assessments from the Demodex blepharitis program. We have not conducted and do not intend to conduct any preclinical studies with TP-03 for the treatment of MGD in order to advance to Phase 2a.

\*\*\* We intend to leverage all preclinical, Phase 2 and Phase 3 data from the TP-03 Demodex blepharitis program. We intend to conduct in vitro or in vivo bioequivalence studies with our preservative-free formulation to compare it to the current preserved formulation of TP-03 in Demodex blepharitis after NDA submission and file a supplement.

† We intend to leverage systemic preclinical data from our TP-03 program and augment with additional dermal preclinical studies to select formulation in order to advance to Phase 1/2, which we intend to conduct outside the United States. We may need to address this approach with the FDA if we were to conduct a clinical trial in the United States. We have not conducted any preclinical studies in rosacea with TP-04 to date.

†† In relation to Lyme disease prevention and community malaria reduction, we intend to leverage oral systemic preclinical data from our TP-03 program as well as third-party oral systemic preclinical studies for Lyme disease prevention or community malaria reduction, respectively

(and will not conduct our own preclinical studies for Lyme disease prevention and community malaria reduction). The formulations used in preclinical studies use the common approach of a gavage that is scaled as appropriate for use in animals. However, human administration, while continuing to be oral, will take the form of a tablet or capsule. We have received FDA feedback from our pre-IND meeting and the FDA has accepted our IND application for Lyme disease prevention. We plan to commence a Phase 1 trial in 2021, and further intend to conduct additional trials based on these preclinical studies. In relation to community malaria reduction, we may conduct our trials outside the United States.

# TP-05 Oral Tablet: Long-Acting Endectocide for Lyme Disease Prevention and Community Malaria Reduction

## Lyme Disease Prevention Represents a Significant Unmet Need

### Lyme Disease: Over 300k US cases/year

- Bacterial infection carried by ticks
- >30M people in US at risk of exposure
  - ~20M in high incidence geographies
- TP-05 is a non-vaccine based preventative therapeutic in development that targets ticks directly
  - Based on sustained PK levels in the blood, a more predictable approach compared to immunogenicity
  - Potential for >95% reduction in Lyme risk
    - Kills 70% of ticks within 4 hrs, 99% @ 8 hrs
    - Potential to prevent bacterial transmission (24-72 hrs)



## TP-05 IND Accepted and Callisto Ph 1 Trial Initiated

### IND accepted in May 2021

- Callisto trial will assess safety, PK, and tick kill objectives
  - To evaluate the safety and tolerability of TP-05 in healthy volunteers
  - To evaluate the pharmacokinetics (PK) of TP-05 in blood, skin, renal PK and food effect
  - To explore TP-05 treated blood for tick kill (ex-vivo) and human metabolites
- Callisto trial will also inform approach for community malaria reduction



# Key Upcoming Catalysts to Advance our Growth

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Saturn-2 Topline  
Results  
**1Q 2022**



TP-03 NDA Filing  
**2022**



TP-05 Callisto Phase  
1 Trial Completion  
**1H 2022**



TP-03 MGD Phase  
2a Trial Initiation  
**4Q 2021**



Topical Rosacea Phase  
1/2 Trial Initiation  
**4Q 2021**

# Closing Remarks

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- **Saturn-1 Phase 2b/3 pivotal trial results highly positive** and further supports TP-03 clinical and regulatory success
- TP-03 clinical outcomes and disease prevalence and impact studies validate attractive product profile for **potential first FDA-approved Demodex blepharitis therapeutic**, if approved
- Tarsus near-term clinical milestones, experienced executive team, and Board additions position company to become an **eye care pharmaceutical leader**
- Pipeline advancing with **TP-05 Callisto Phase 1 trial for Lyme disease prevention initiated** and key upcoming clinical milestones in next 12 months