



Tarsus Pharmaceuticals

Jefferies Virtual London Healthcare Conference
November 17, 2020



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Corporate Highlights

Potential for first-ever FDA-approved therapeutic for Demodex blepharitis. Significant market opportunity with no approved therapies

Completed five clinical trials, including two Phase 2b randomized control trials.
Consistently met safety and efficacy endpoints

Commenced Phase 2b/3 enrollment in September 2020 (Saturn-1 trial)

Demodex blepharitis is a significant market opportunity with estimated cases in the U.S. as high as 25 million. We believe it parallels the dry eye market¹

Pipeline with novel API advancing to Phase 2a proof of concept in MGD², and Phase 1/2 trials in rosacea³, Lyme disease and malaria⁴

1 – The market for Demodex blepharitis may not be similar based on differences in the underlying disease, different ECP and patient attitudes, and treatment and/or key assumptions we have not taken into our analysis.

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

3 – 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. We have not conducted any preclinical studies in rosacea with TP-04 to date. See slide [24] (including the footnotes thereto) for more information.

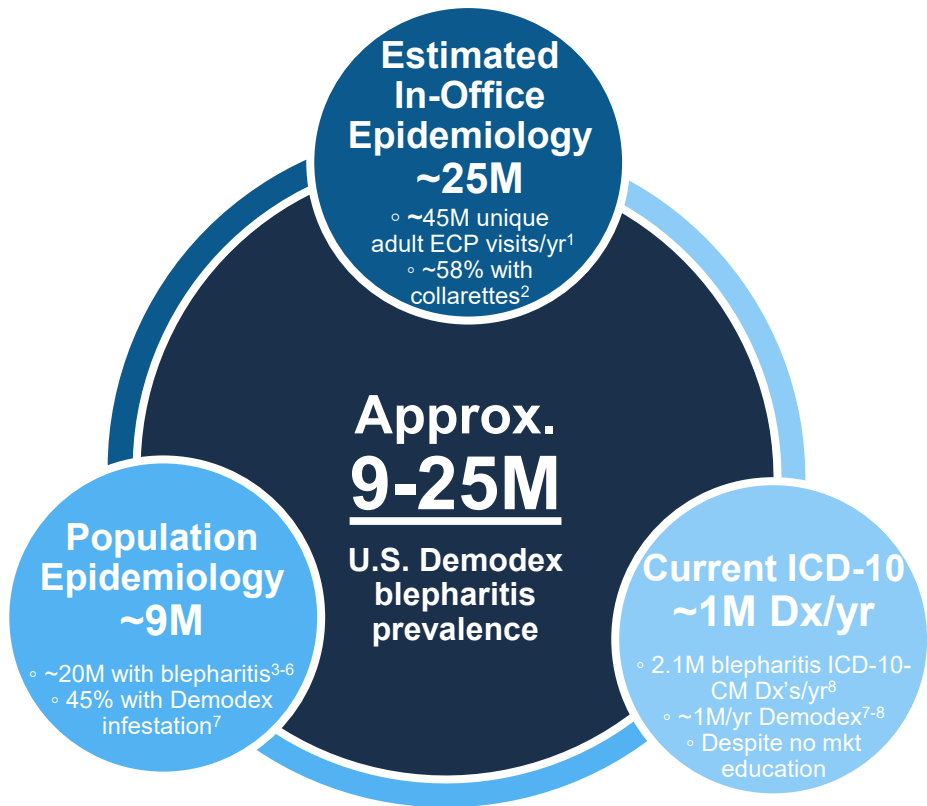
4 –In relation to Lyme disease and malaria, we intend to leverage oral systemic preclinical data from our TP-03 program as well as third-party oral systemic preclinical studies for Lyme disease or community malaria reduction, respectively (and will not conduct our own preclinical studies for Lyme disease and malaria). See slide [24] (including the footnotes thereto) for more information.

Our Mission

To discover and deliver breakthrough treatments to transform the lives of patients with common and poorly treated diseases, **starting with the eye**

Blepharitis is a Large and Underserved Market in Eye Care

Epidemiology of Demodex Blepharitis



Largely Underdiagnosed, Education Needed	~ 58% of <u>all patients</u> in the eye clinic have collarettes ² but current impression of only 10-15% of blepharitis cases
Significant head start on Diagnosis	2.1M ICD-10 Blepharitis Dx's/yr ⁸
Blepharitis Routinely Causes	Eyelids to become red, irritated and itchy, with debris on the eyelashes. ⁹
Blepharitis Can Lead To	Blurring of vision, missing or misdirected eyelashes, and inflammation of other eye tissue, particularly the cornea ⁴
Concomitant Dry Eye	Significant overlap in Dry Eye patients. Demodex prevalent in ~69% of DE patients ⁵
Blepharitis and Surgery	Important factor for maximizing surgical outcomes: 67% of Cataract Patients have Demodex blepharitis ⁶
Contact Lens Drop-out	Studies have shown a direct correlation between Demodex blepharitis and Contact Lens intolerance ¹⁰
Prescription Treatment	None

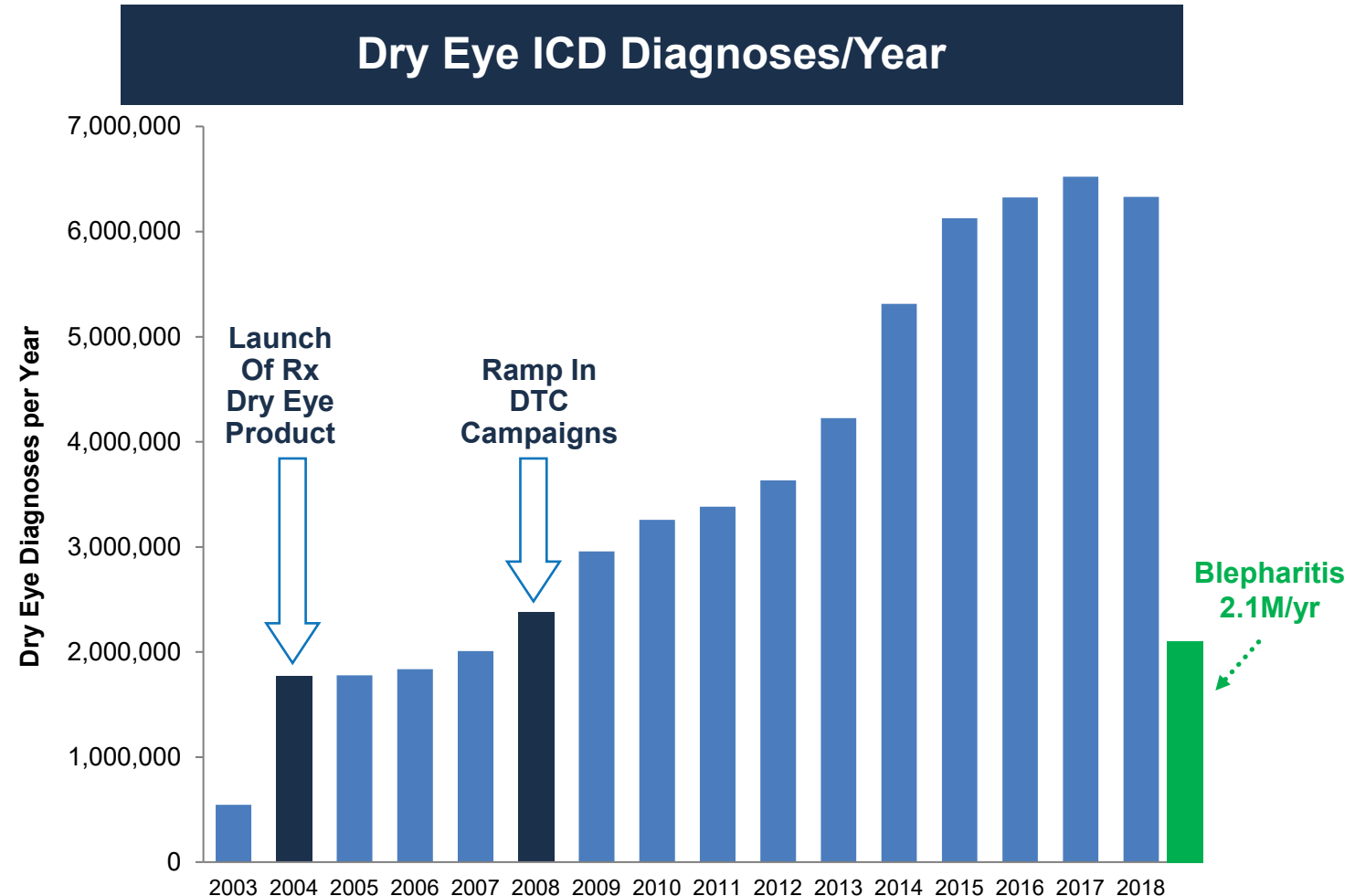
1. Wilson J Ophthalmology 2015, 435606, 2014; 2. Tarsus collarette prevalence study; 3. MGD Report IOVS, Special Issue 2011, Vol. 52, N. 4; 4. American Optometric Association; 5. Cheng Cornea Sept 2020; 6. IOVS June 2020; 7. Zhao - Ophthalmic Epidemiology, 19(2), 95-102, 2012; 8. Symphony Claims Data Analysis; 9. Harmon, Market Scope Dry Eye Analyst Report, 2014 10. Tarkowski W, Moneta-Wielgoś J, Młocicki D. Demodex sp. as a Potential Cause of the Abandonment of Soft Contact Lenses by Their Existing Users. Biomed Res Int. 2015;2015:259109

Blepharitis has Potential Similarities to Dry Eye Market 15 Years Ago

Potential Large Latent Demand for a New Therapy

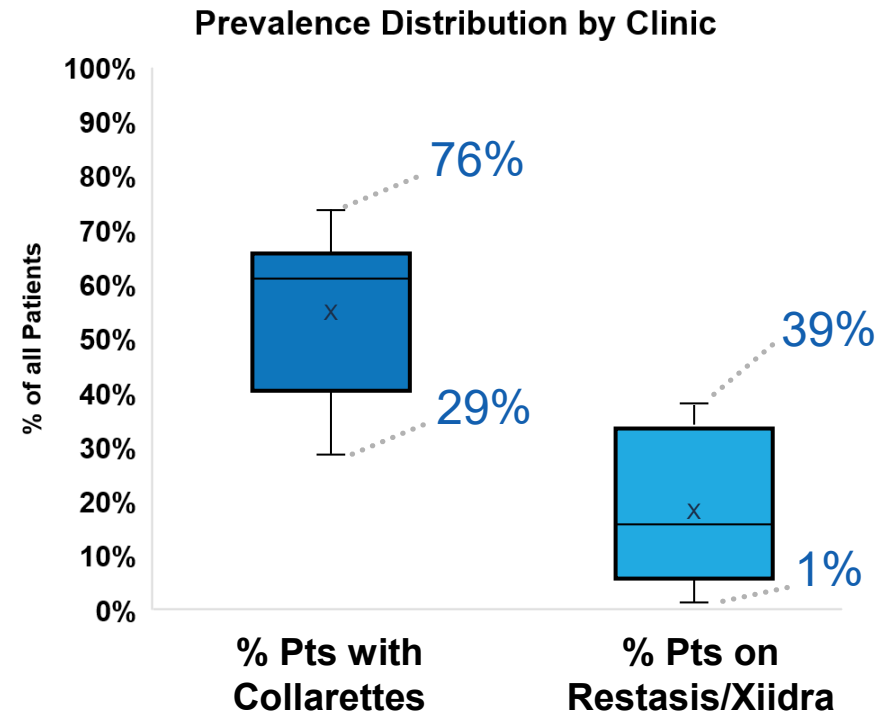
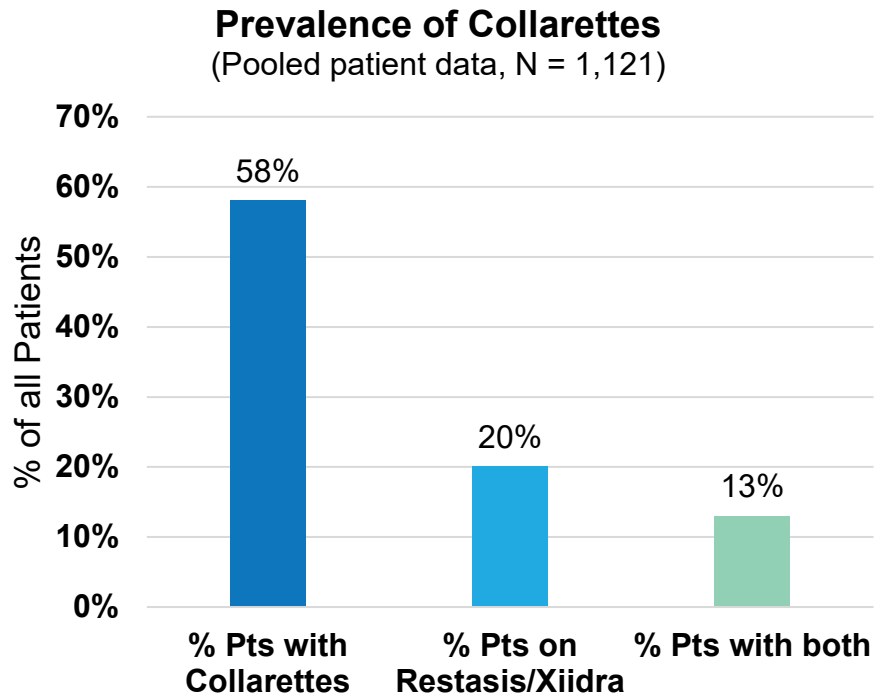
- Dry eye is a similar ocular surface disease to Blepharitis, that is likewise treated by ECPs*
- Large untapped patient population that was activated through education of ECPs and patients
- In 2003, no approved dry eye therapeutics
 - With approval of a prescription therapeutic and concurrent ECP and patient education, diagnosis rate increased 12 times
- Blepharitis already has 2.1 million diagnoses per year, despite no approved therapies
- Collarette prevalence study suggests Demodex blepharitis prevalence > 2 times dry eye prescriptions across MD and OD clinics

**The market for Demodex blepharitis may not be similar based on differences in the underlying disease, different ECP and patient attitudes, and treatment and/or key assumptions we have not taken into our analysis.*



Half of All Patients Entering Clinic have Collarettes

- Since Demodex is newly appreciated as a cause of blepharitis, Tarsus performed the first-ever Demodex blepharitis in-clinic prevalence study
- Methods: every consecutive patient seen by the clinic is evaluated for
 1. Presence of collarettes (the pathognomonic sign and key diagnostic for Demodex blepharitis)
 2. Whether they have an active Rx for dry eye (Restasis® or Xiidra®)
- N = 1,121 consecutive patients, 8 clinics (MDs and ODs, geographically diverse)



Note: Data from Tarsus Collarette Prevalence Study
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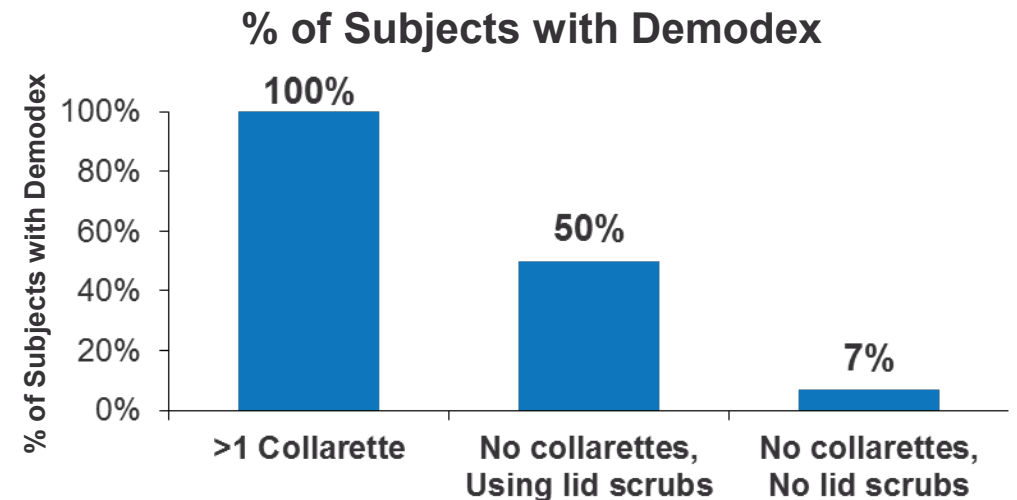
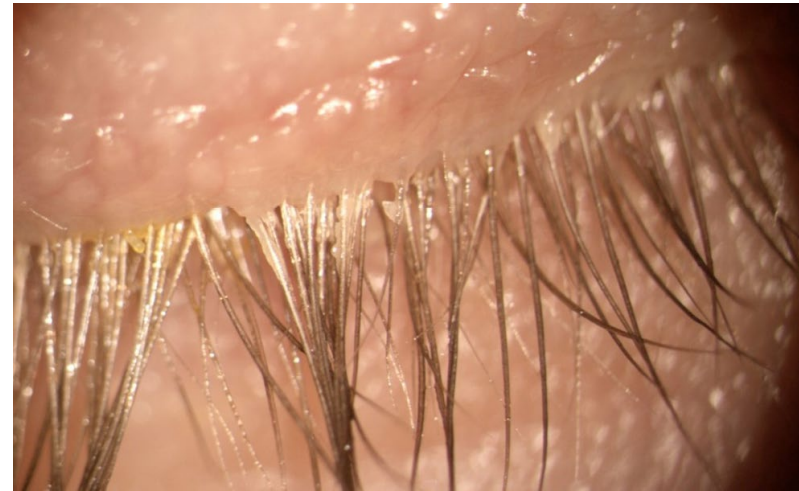
Collarettes Are Pathognomonic Sign of Demodex Infestation

Collarettes Are Composed of Mite Waste Products and Eggs¹

- Regurgitated undigested material combined with epithelial cells, keratin, and mite eggs
- Contain digestive enzymes, which cause irritation

Easily and Rapidly Diagnosed with Standard Eye Exam

- Demodex mites found on 100% of lashes with collarettes²
- Collarettes found in ~ 58% eye care patients³



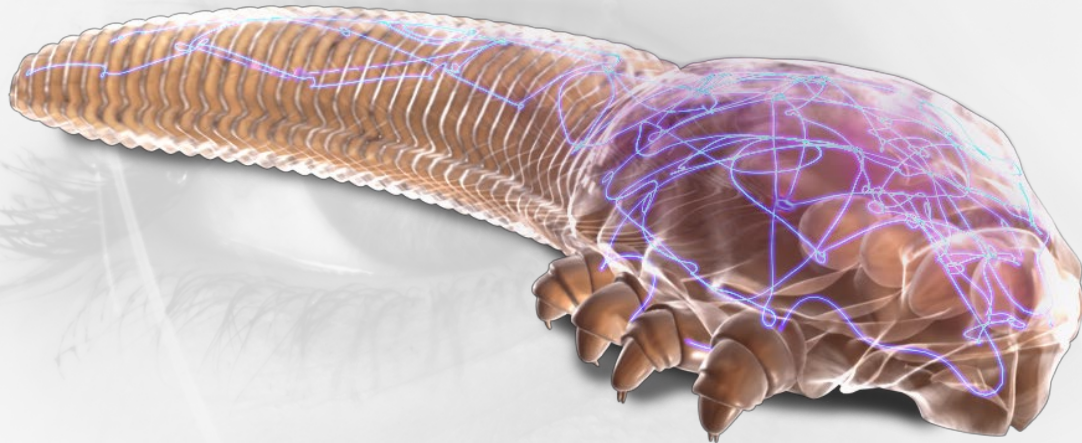
1. Fromstein 2018

2. Gao et al., Invest Ophthalm and Vis Sci, September 2005, Vol. 46, No. 3089-3094

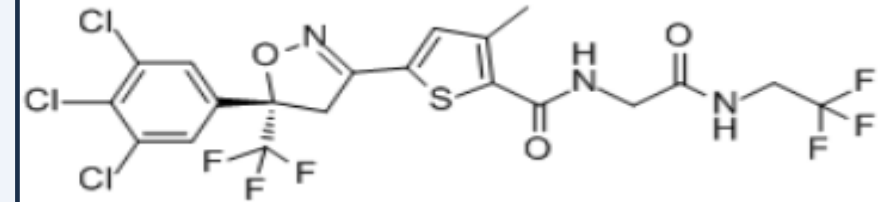
3. Tarsus Collarette Prevalence Study

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

TP-03 is designed to paralyze the mite nervous system through parasite-specific GABA inhibition










Lotilaner



- Potent non-competitive antagonist of insect and arachnid GABA-Cl channels
- Highly lipophilic molecule, which may promote its uptake in the oily sebum of the hair follicle, where the mites reside
- **Tarsus has licensed worldwide rights to lotilaner for all human uses**

TP-03 is a Novel Drug Designed to **Treat Demodex Blepharitis** by **Eradicating Mites and Collarettes**¹

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



*BID means twice per day

1. TP-03 Product profile based on Saturn-1 Trial Design

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Extensive Clinical Trial Program for TP-03

Trial / Study	Design	Endpoints	Results Achieved		Status
PoC: Mercury	Ex-vivo mite testing on 80 mites	Ex-vivo mite death count	100% mites dead within 24 hours (p < 0.001)		
Clinical Trials			Collarette Cure Rate**	Mite Eradication Rate	
P2a: Mars *	28-day BID dosing, single arm (n=15) Pilot formulation	Collarette grade Mite density Safety	86% at 28 days (p < 0.05)	57% at 28 days (p < 0.05)	
P2b: Jupiter *	28-day BID dosing, randomized 1:1 (n=60) Pilot formulation	1° – Mite density Safety 2° – Collarette grade	88% at 28 days (p < 0.001)	67% at 28 days (p < 0.005)	
P2a: Io **	42-day BID dosing, single arm (n=18) Current formulation	1° – Collarette cure rate 2° - Mite eradication Safety	72% at 42 days (p < 0.05)	78% at 42 days (p < 0.05)	
P2b: Europa **	42-day BID dosing, randomized 1:1 (n=54) Current formulation	1° – Collarette cure rate 2° – Mite eradication 2° – Redness Composite Safety	80% at 42 days (p < 0.001)	73% at 42 days (p = 0.003)	
P2b/3: Saturn-1 ** †	42-day BID dosing, randomized 1:1 (n≥350) Current formulation	1° – Collarette cure rate 2° – Mite eradication 2° – Redness Composite Safety	Trial initiated in September 2020		
P3: Saturn-2 ** ††	42-day BID dosing, randomized 1:1 (n=350) Current formulation	1° – Collarette cure rate 2° – Mite eradication 2° – Redness Composite Safety	Initiate trial in 2021		

Two Pivotal Trials

* The Mars and Jupiter trials used collarette grade as an endpoint, which has been translated into a collarette cure (defined as <10 collarettes). This is different from the collarette cure (defined as ≤2 collarettes) endpoint used in Io, Europa, Saturn-1 and the planned Saturn-2 trials. The Mars and Jupiter trials also used mite density as an endpoint, which is different from mite eradication. Mite density is translated into mite eradication, which is defined as zero mites per lash consistently throughout trials.

** Primary endpoint in Io, Europa, Saturn-1 and intended in Saturn-2 is collarette cure based on collarette grade.

† In connection with our IND application, a “no-objection” letter was received from the FDA regarding the trial design of the Saturn-1 trial.

†† Saturn-2 design is highly comparable to that of Saturn-1 with respect to which the FDA raised no-objection and we expect to update the IND protocol prior to commencing Saturn-2.

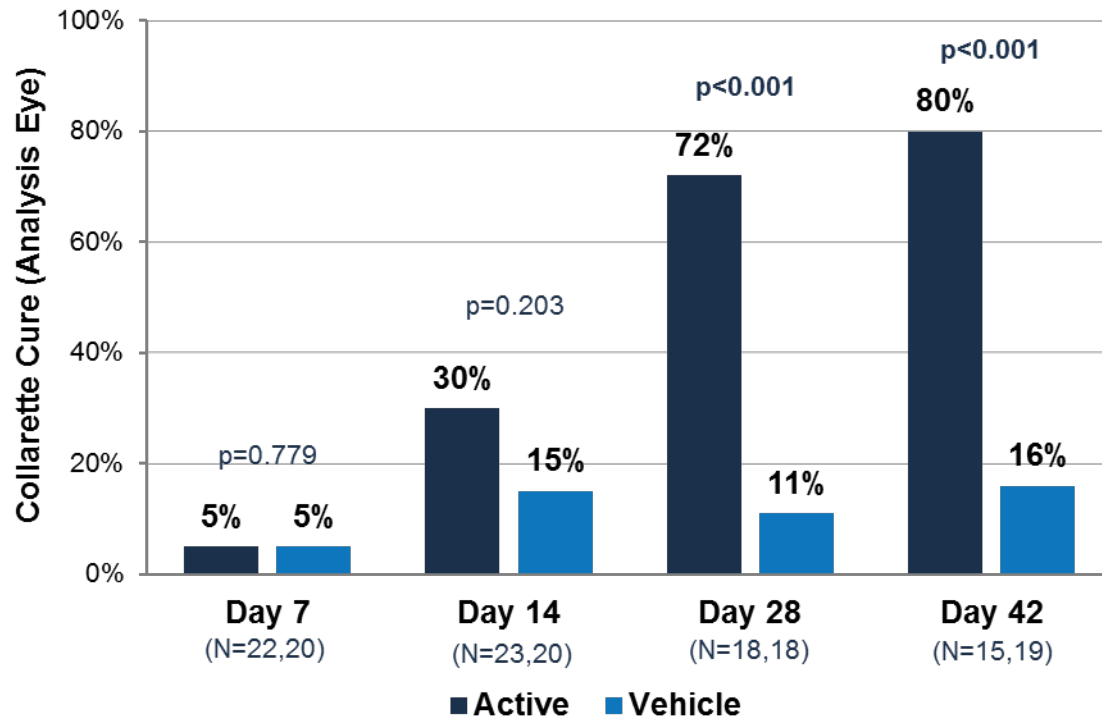
Cure of Collarettes with BID Use of TP-03



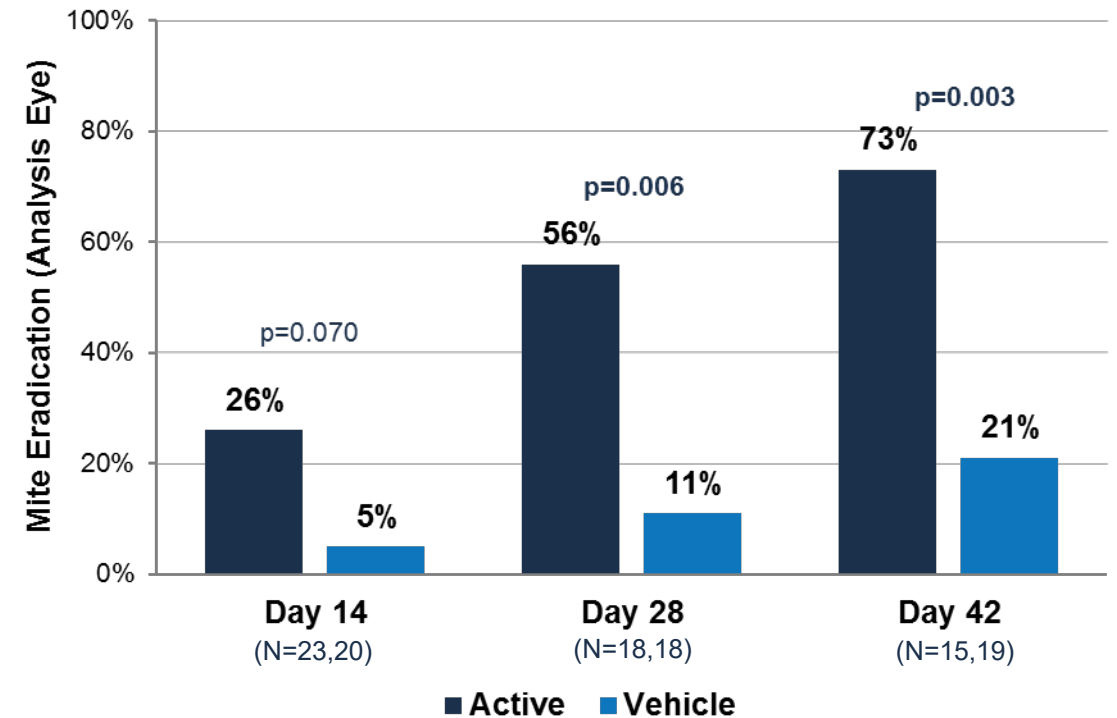
Europa Phase 2b: Results Consistent with Jupiter Trial

Primary and secondary efficacy endpoints same as Saturn-1 trial

Collarette Cure (0-2 collarettes)*



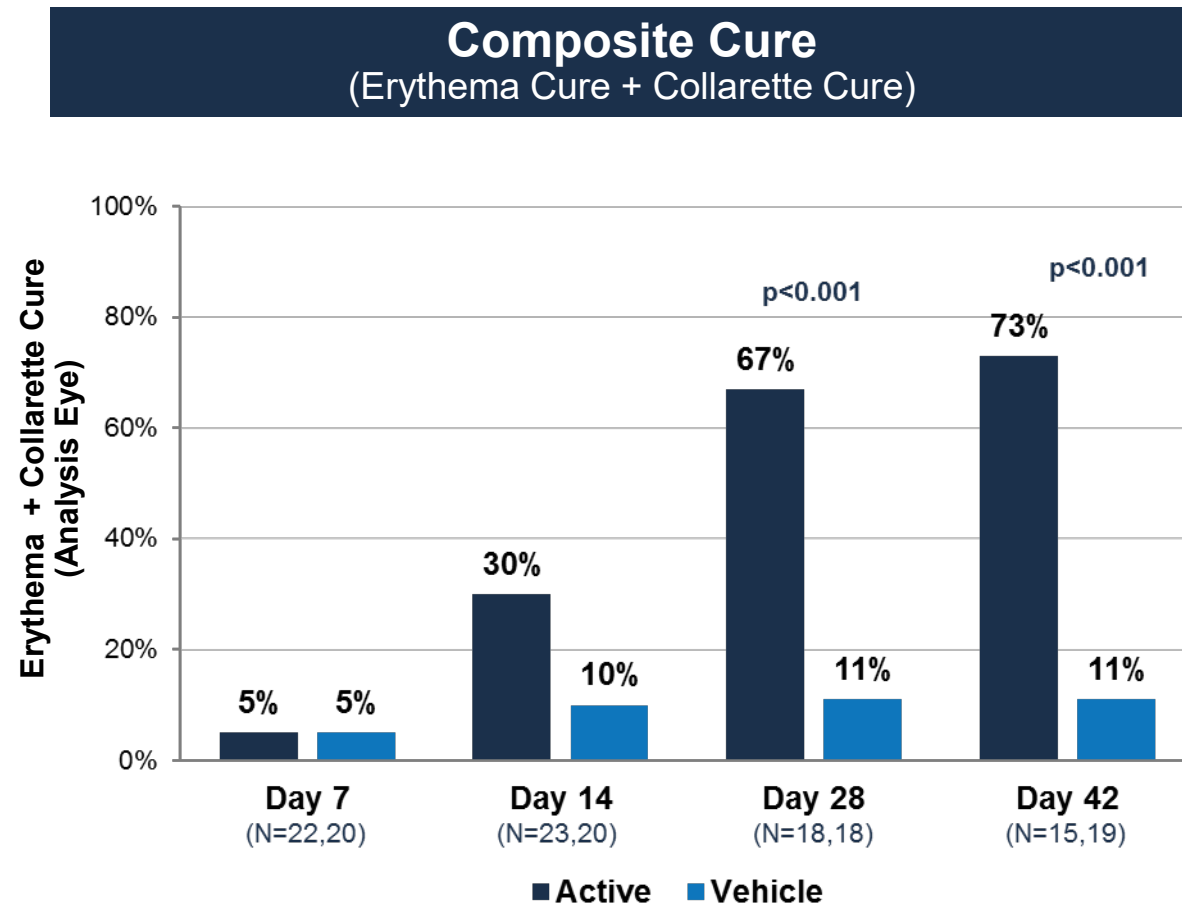
Mite Eradication (0 mites)



* The primary efficacy endpoint was the proportion of patients experiencing a cure based on collarette grade of two or fewer collarettes on the eyelid, or collarette cure, as compared to the vehicle control, at day 42.

Europa Phase 2b: Statistically Significant Composite Cure Rate

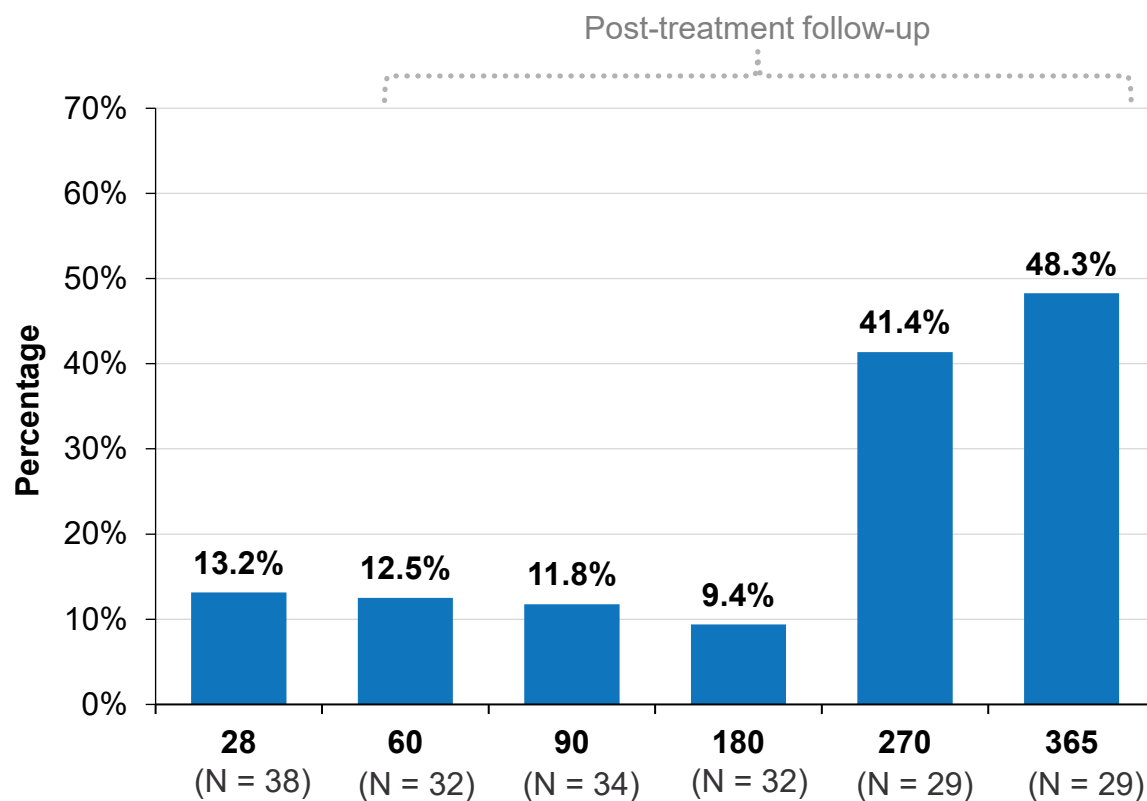
Lid erythema cure + collarette cure, FDA-requested additional secondary endpoint



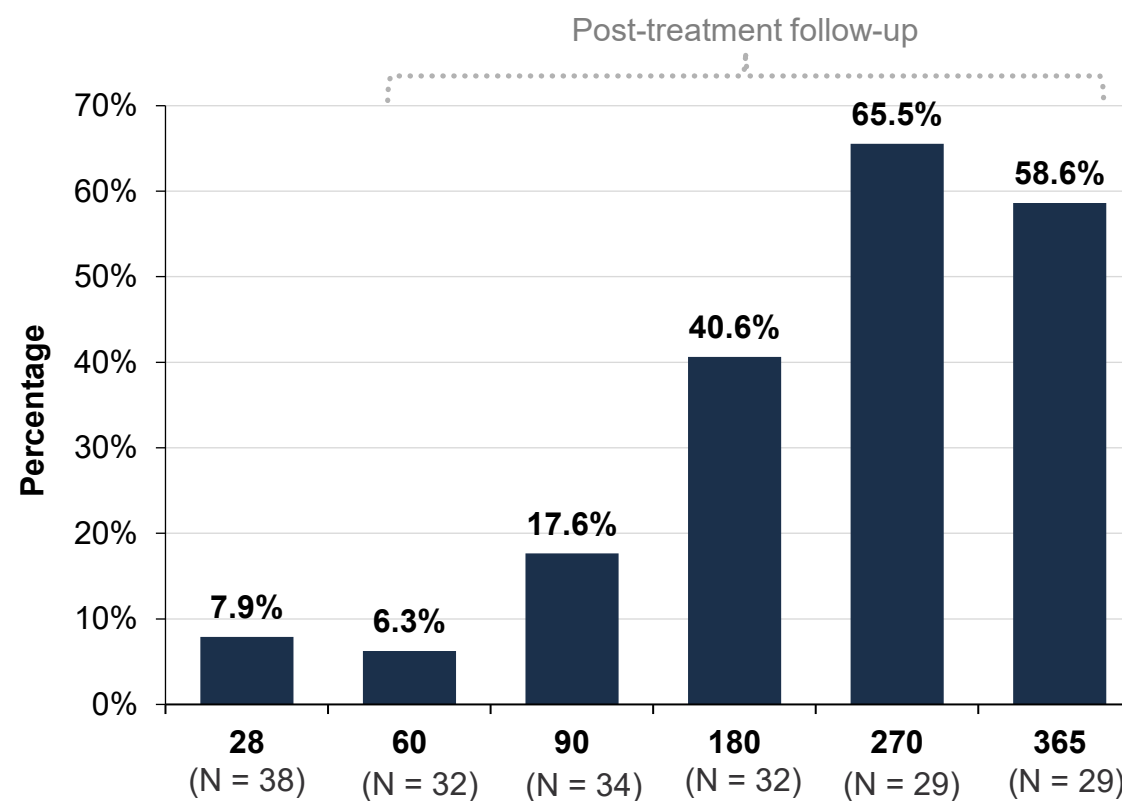
TP-03 Phase 2 Clinical Data Show Recurrence Rate of Clinical-Grade Demodex Blepharitis Post-Treatment

Post treatment data from Mars & Jupiter trials show recurrence of both collarettes & mite density

>10 Collarettes on Lid



Mite Density of 1.0 or More



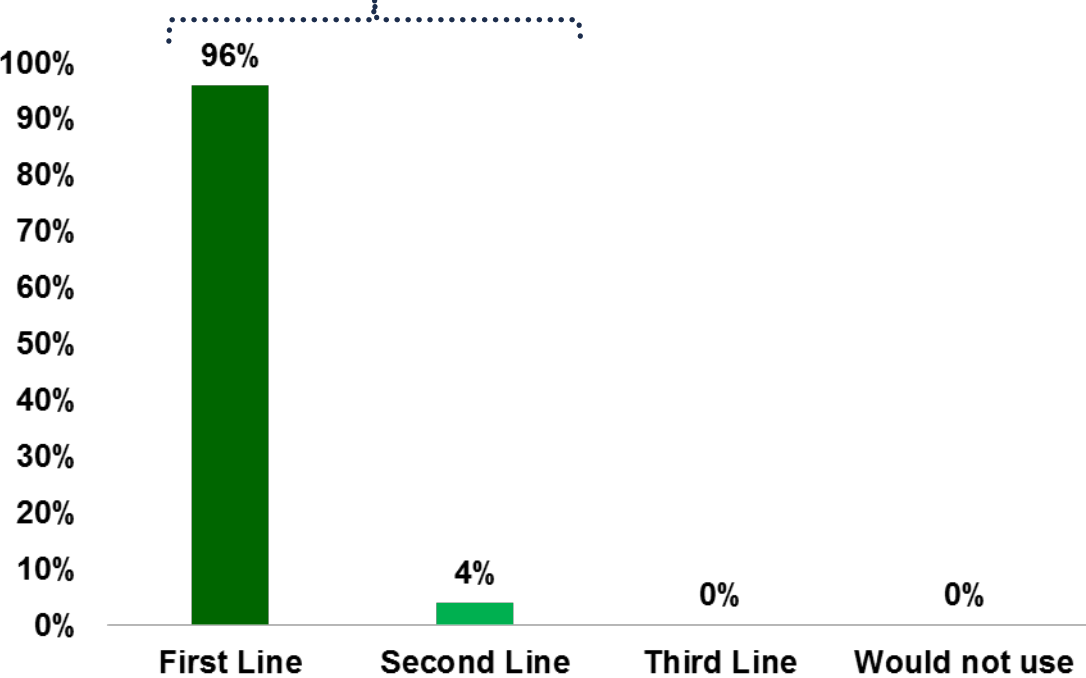
Data account for presence of collarettes or mites on either eye, (upper eyelid for collarette score)

Market Research Shows Positive Reaction from Providers and Patients

After exposure to information on collarettes, Demodex blepharitis and TP-03 Phase 2 data

Clinician Prescribing Intention

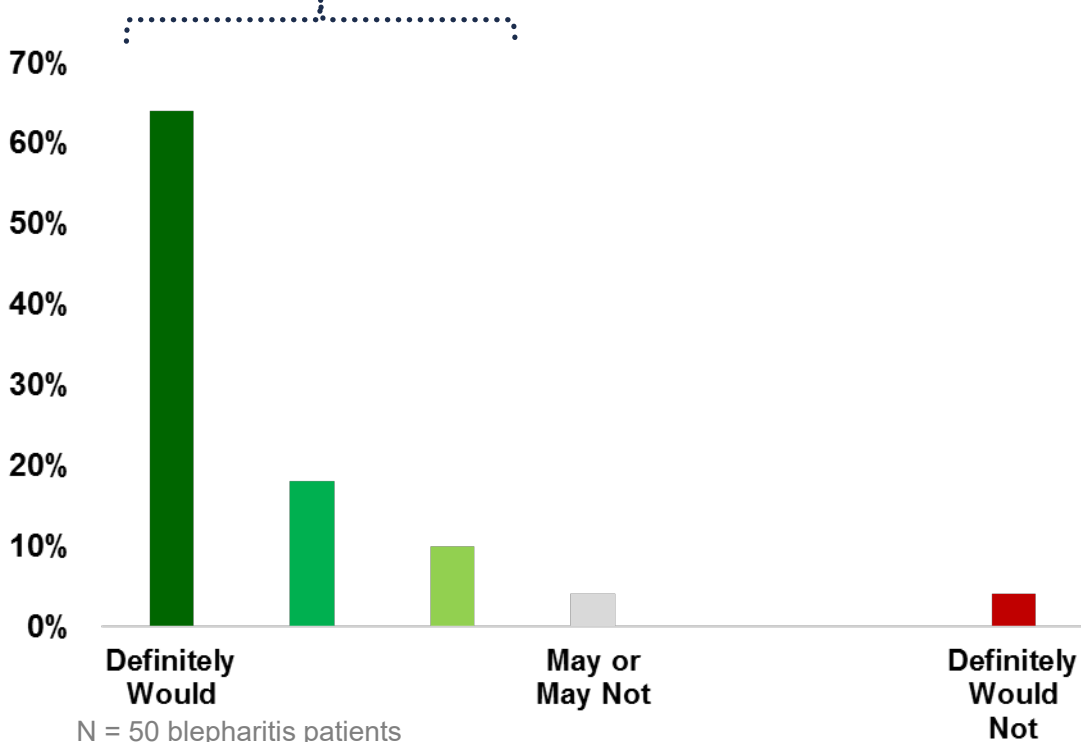
100% of ECPs indicated would prescribe 1L or 2L for Demodex blepharitis



N = 50 eye care providers (25 MDs, 25 ODs)
Market research sponsored by Tarsus
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Patient Intention to Seek a Doctor

92% of blepharitis patients indicated would likely seek a doctor and ask about TP-03



N = 50 blepharitis patients

TP-03 has **Significant Market Potential** in Demodex Blepharitis

Opportunity comparable to established ophthalmic therapeutics

Large addressable patient population

- High prevalence of an estimated 25 million patients and untapped educational opportunity similar to Dry Eye*
- 2.1 million current ICD-10 blepharitis diagnoses per year in U.S. (estimated 45% of these with Demodex infestation)
- Besides blepharitis, patients commonly present at ECPs with other conditions such as dry eye, cataracts, and contact lens discomfort

ECPs are generally believed to be comfortable treating ocular surface disease and respond to marketing education

- 25k active prescribers
- We have observed a significant willingness to prescribe by ECPs

Potential for favorable reimbursement







- Potential to be the first approved prescription treatment for Demodex blepharitis, strong and predictable outcomes drive value for payers
- We believe a novel treatment will drive compelling pricing and modest discounts

We Believe There are 3 Keys to Success

1. Educate ECPs about the prevalence of Demodex blepharitis and the safety and efficacy of our products
2. Highlight prevalence, impact, and simplicity of diagnosis of Demodex blepharitis
3. Patient focused education and marketing that increases awareness and patient identification

Pipeline with Different Formulations of Novel API

Anticipated clinical trial events in our programs in 2021

Candidate	Indication	Formulation	Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Future Milestones *	Worldwide Rights
TP-03	Demodex blepharitis		▶				2021: Top line data results for Phase 2b/3 Saturn-1 trial 2021: Initiate Phase 3 Saturn-2 trial	
	Meibomian Gland Disease (MGD)	 (Eye drop)	▶				Initiate Phase 2a proof of concept**	tarsus 
	Demodex blepharitis (Preservative-Free)		<i>Preservative-free formulation to be tested after NDA submission</i>				Bioequivalence studies (US) ***	
TP-04	Rosacea	 (Topical)	▶				2021: Initiate Phase 1/2 trial †	tarsus 
TP-05	Lyme Disease	 (Oral)	▶				2021: Submit IND; Initiate Phase 1/2 trial ††	tarsus 
	Malaria		▶				2021: Initiate Phase 1/2 trial ††	

* 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 and malaria, 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 or community malaria reduction, respectively (and will not conduct our own preclinical studies for Lyme disease and malaria). 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. Subject to FDA feedback from our planned pre-IND meeting, we intend to conduct Phase 1/2 trials in these indications based on these preclinical studies. In relation to malaria, we may conduct our Phase 1/2 trial outside the United States. While we plan to discuss this approach for Lyme disease in a planned pre-IND meeting with the FDA, the FDA may reject our use of data from these preclinical studies and require us to conduct additional preclinical studies before advancing to clinical trials, which may delay our expected timelines for approval and increase costs.

Tarsus Summary

- TP-03 is a novel therapeutic with potential to be the first FDA-approved therapeutic and the standard of care for the treatment of Demodex blepharitis
- Clinical efficacy and safety endpoints consistently achieved across multiple Phase 2 studies
- Phase 2b/3 Saturn-1 **currently enrolling and treating patients, topline expected in 2021**, followed by initiation of Phase 3 Saturn-2 trial in 2021¹
- Clinical stage pipeline with potential applications to other indications in MGD, rosacea, Lyme disease, and malaria
- Multiple clinical events anticipated in 2021

1. Both subject to the impact of the ongoing COVID-19 pandemic

