



Tarsus Pharmaceuticals Announces Positive Results of the Mars study, a Phase 2a Study of the Efficacy and Safety of TP-03 to Treat Demodex Blepharitis, at ARVO 2020 Virtual Meeting

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This first clinical trial of TP-03 for Demodex Blepharitis showed rapid, complete, and durable efficacy with no serious adverse effects.

IRVINE, Calif., June 15, 2020 /PRNewswire/ -- Tarsus Pharmaceuticals, a clinical-stage biopharmaceutical company, today announced positive results of its Phase 2a Mars Study and the release later this month of the results of a Phase 2b randomized controlled study. The Mars study demonstrated that the use of TP-03 for 4 weeks was well-tolerated and showed promising efficacy in the treatment of Demodex Blepharitis with treatment effects persisting for at least 90 days.

"My colleagues and I are excited that there is a possible new therapy that targets the underlying cause of disease for nearly half of all blepharitis patients," said Dr. Roberto Gonzalez-Salinas, the principal investigator for the study conducted at the Asociación para Evitar la Ceguera in Mexico City.

Mars was a single-arm, open-label study that evaluated the safety and efficacy of TP-03 in 15 participants with Demodex Blepharitis. The prespecified efficacy endpoints were improvement in collarette score and mite density. Participants dosed one drop of TP-03 in each eye BID for 28 days. Results showed statistically significant decreases in mean collarette score and mite density beginning at day 14 and continuing throughout the study period of 90 days with no adverse events reported. Specific results were:

- **Collarette Score:** The mean grade showed statistically significant improvement from baseline to day 14 and had a 2-grade improvement overall on a 4-point scale by the end of the treatment period at day 28.
- **Mite Eradication:** The average mites/lash showed statistically significant improvement from baseline to day 14 and had a 10-fold improvement from baseline by the end of the treatment period at day 28.
- **Safety:** No treatment-related adverse events were reported and there were no clinically significant changes in visual acuity, intraocular pressure and slit lamp biomicroscopy findings including in corneal staining.

"We are excited that TP-03 has shown rapid, complete, and durable efficacy across both measures with a tolerable and safe eyedrop," said Tarsus CEO Bobak Azamian, MD, PhD. "These results are the beginning of a strong, consistent data set we are generating with TP-03 to treat the underlying cause of Demodex Blepharitis and other conditions."

Tarsus will release results of the Jupiter Study, a Phase 2b Randomized Controlled Trial to Evaluate the Safety and Efficacy of TP-03 for the Treatment of Demodex Blepharitis at the American Optometric Association's virtual meeting on June 26 at 12:30 pm EDT. The company plans to file an IND for TP-03 to treat Demodex Blepharitis and begin a Phase 3 trial later this year. Its clinical pipeline also includes studies in meibomian gland disease (MGD) and rosacea.

About Demodex Blepharitis

Blepharitis is a common ocular condition characterized by inflammation of the eyelid, which can impact the anterior or posterior lid or both. People with anterior blepharitis typically have red, irritated, or itchy eyelids with debris on the eyelashes. Blepharitis affects at least 20 million Americans and is one of the most common reasons people visit an eye doctor. It can be caused by multiple factors including infestation of Demodex mites.

Demodex mites are the most common ectoparasite found on humans. There are two species of Demodex – *folliculorum* and *brevis* – that live on the skin of the face and eyelids. While they are highly prevalent in low numbers, an infestation of *Demodex folliculorum* mites is implicated as a cause of blepharitis in 45% of cases.¹

Currently, there are no FDA approved prescription treatments for Demodex Blepharitis. If left unmanaged, Demodex Blepharitis may lead to tear film instability with fluctuating and blurred vision, lid and lash abnormalities, inflammation of the conjunctiva and surrounding skin, suboptimal surgical outcomes, contact lens intolerance and reduced wear time, noticeable eye and eyelid redness, and lower patient quality of life.

About TP-03

TP-03 is a novel, topical ophthalmic drug that specifically targets the mite's nervous system to kill the mites, thereby treating the underlying cause of disease. The agent has shown consistent results across four Phase 2 studies and almost 100 treated patients to date. Patients report that the drop is comfortable, and no patients in the study discontinued use due to tolerability. TP-03 is currently being developed in a multi-dose, preserved formulation and is expected to begin Phase 3 trials this year.

About Tarsus Pharmaceuticals

Tarsus is a privately held, clinical-stage biopharmaceutical company whose mission is to bring transformational new drugs to eye care and other specialties, starting with Demodex Blepharitis. Tarsus was founded in 2017 and is headquartered in Irvine, California. For more information, please visit tarsusrx.com and follow us on Twitter @tarsusrx.

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