# Tarsus to Present Additional Saturn-2 Pivotal Phase 3 Trial Data at the American Academy of Optometry 2022 Annual Meeting

October 25, 2022

*Saturn-2 follow-up data to be presented on TP-03 for the treatment of Demodex blepharitis*

*Tarsus recently submitted NDA to the FDA for TP-03*

*Data from an investigator-initiated trial evaluating meibomian gland atrophy in patients with Demodex blepharitis will also be presented*

IRVINE, Calif., Oct. 25, 2022 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), whose mission is to address patient needs, starting with eye care, through the application of proven science and new technology, today announced that additional efficacy results from the Saturn-2 pivotal Phase 3 trial of TP-03 (lotilaner ophthalmic solution, 0.25%) in *Demodex* blepharitis patients will be presented at the upcoming American Academy of Optometry 2022 Annual Meeting in San Diego, California.

Additionally, data from an investigator-initiated study evaluating a potential correlation between meibomian gland atrophy and collarettes, the pathognomonic sign of *Demodex* blepharitis, will be presented.

“We are encouraged by the strong and consistent data from our Saturn-2 pivotal Phase 3 trial, which further demonstrates the potential of TP-03, if approved, in treating *Demodex* blepharitis,” said José Trevejo, M.D., Ph.D., Chief Medical Officer of Tarsus. “Additionally, new research studying a potential correlation between *Demodex* blepharitis and meibomian gland atrophy underscores the importance of *Demodex* as a contributing factor to meibomian gland disease.”

Tarsus recently submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for TP-03 based on the Saturn-1 and Saturn-2 pivotal trial results, both of which met the primary endpoint and all secondary endpoints, as well as additional studies. There are currently no FDA-approved treatments for *Demodex* blepharitis.

The posters being presented at the meeting are listed below:

- **Safety & Efficacy of Lotilaner Ophthalmic Solution, 0.25% in Treating *Demodex* Blepharitis Results of the Phase III Saturn-2 Trial**; Paul Karpecki, O.D., et al.
  - Date: Thursday, October 27, 2022, 4:30-6:30 p.m. PT
  - Location: Poster Board #35
- **Meibomian Gland Atrophy in Patients with *Demodex* Blepharitis**; Cecelia Koetting, O.D., Elizabeth Yeu, M.D.
  - Date: Friday, October 28, 2022, 1:00-3:00 p.m. PT
  - Location: Poster Board #124

Tarsus’ Chief Commercial Officer, Aziz Mottiwala, will also participate in the American Academy of Optometry’s 2022 virtual press conference to discuss the TP-03 pivotal trial results and the company’s *Demodex* blepharitis educational campaign. The virtual press conference will be on Tuesday, October 25, 5:00-7:00 p.m. PT and is accessible via the following link:
https://vimeo.com/optometry/2022aaopressconference

**About TP-03**
TP-03 (lotilaner ophthalmic solution, 0.25%) is a novel, investigational therapeutic designed to resolve the signs of *Demodex* blepharitis by targeting and eradicating the root cause of the disease – *Demodex* mite infestation. Lotilaner is a well-characterized agent that eradicates *Demodex* mites by selectively inhibiting the GABA-Cl channels. It is a highly lipophilic molecule, which may promote its uptake in the oily sebum of the eye lash follicles where the mites reside. TP-03 was evaluated in two pivotal trials collectively involving more than 800 patients. Both trials met the primary endpoint and all secondary endpoints, with statistical significance and no serious treatment-related adverse events. Most patients found TP-03 to be neutral to very comfortable. The most common treatment-related ocular adverse event occurring at a frequency of >2% in TP-03 treated patients was instillation site pain/burning/stinging; most adverse events were mild with few moderate in severity. If approved, TP-03 may offer treatment for millions of patients with *Demodex* blepharitis. TP-03 is now also being studied for the treatment of Meibomian Gland Disease in patients with *Demodex* mites.

**About *Demodex* Blepharitis**
Blepharitis is a common lid margin disease that is characterized by eyelid margin inflammation, redness and ocular irritation. *Demodex* blepharitis is caused by an infestation of *Demodex* mites, the most common ectoparasite found on humans and accounts for over two-thirds of all blepharitis cases. *Demodex* blepharitis may affect as many as 25 million Americans based on an extrapolation from the Titan study indicating 58% of patients presenting to U.S. eye care clinics have collarettes, a pathognomonic sign of *Demodex* infestation, and that at least 45 million people annually visit an eye care clinic. *Demodex* blepharitis can have a significant clinical burden and negative impact on patients’ daily activities. The Titan study also showed that current management tools, such as tea tree oil and lid wipes, are ineffective at treating *Demodex* blepharitis. Currently, there are no FDA-approved treatments for *Demodex* blepharitis.

**About Tarsus Pharmaceuticals, Inc.**
Tarsus Pharmaceuticals, Inc. applies proven science and new technology to revolutionize treatment for patients, starting with eye care. Tarsus is advancing its pipeline to address several diseases with high unmet need across a range of therapeutic categories, including eye care, dermatology, and infectious disease prevention. Tarsus is studying two investigational medicines in clinical trials. Its lead product candidate, TP-03, is a novel therapeutic which has demonstrated positive results in two pivotal trials for the treatment of *Demodex* blepharitis, and of which a New Drug Application has been submitted to the U.S. Food & Drug Administration (FDA). TP-03 is also being developed for the treatment of Meibomian Gland Disease, and

currently being studied in a Phase 2a clinical trial. In addition, Tarsus is developing TP-05, an oral, non-vaccine therapeutic for the prevention of Lyme disease, which is currently being studied in a Phase 1b clinical trial.

**Forward-Looking Statements**

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements.” These statements include statements regarding the potential market size for TP-03, future events and Tarsus’ plans for and the anticipated benefits of its product candidates including TP-03 and TP-05, the timing, objectives and results of the clinical trials including the potential complete clinical results of the Saturn-2 trial, anticipated regulatory and development milestones, and the quotations of Tarsus’ management. The words, without limitation, “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these or similar identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Further, there are other risks and uncertainties that could cause actual results to differ from those set forth in the forward-looking statement and they are detailed from time to time in the reports Tarsus files with the Securities and Exchange Commission, including Tarsus’ Form 10-K for the year ended December 31, 2021 filed on March 14, 2022 and the most recent Form 10-Q quarterly filing filed with the SEC on August 11, 2022, each of which Tarsus incorporates by reference into this press release, copies of which are posted on its website and are available from Tarsus 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. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. Any forward-looking statements contained in this press release are based on the current expectations of Tarsus’ management team and speak only as of the date hereof, and Tarsus specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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