Tarsus Announces Positive Topline Results from the Ersa Phase 2a Clinical Trial Evaluating TP-03 for the Treatment of Meibomian Gland Disease in Patients with Demodex Mites

December 11, 2023

TP-03 demonstrated statistically significant and clinically meaningful improvements across two objective measures of MGD, regardless of BID or TID dosing, and was well tolerated

IRVINE, Calif., Dec. 11, 2023 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), whose mission is to focus on unmet needs and apply proven science and new technology to revolutionize treatment for patients, today announced topline results from the Ersa Phase 2a clinical trial evaluating TP-03 (lotilaner ophthalmic solution, 0.25%) administered twice daily (BID) or three times a day (TID) for 12 weeks for the treatment of Meibomian Gland Disease (MGD) in patients with *Demodex* mites.

In this study, TP-03 demonstrated statistically significant and clinically meaningful improvements compared to baseline in two objective measures of the disease – the presence and quality of liquid secretion as measured by the Meibomian Gland Secretion Score (MGSS, scoring range of 0-45), and the number of glands secreting normal (clear) liquid as measured in the central 15 glands of the lower eyelid[1-4].

Specifically, a significant and clinically meaningful increase from baseline was observed in the mean MGSS of 10.5 (±1.6 standard error, SE) and 11.7 (±1.9 SE) for the BID and TID arms, respectively, at Day 85 ($p < 0.001$). The improvement in the mean number of meibomian glands secreting clear liquid from baseline was also statistically significant and clinically meaningful, with an increase of 4.8 (±0.8 SE) and 5.3 (±1.1 SE) glands for the BID and TID arms, respectively, at Day 85 ($p < 0.001$). Collarette cure and lid margin erythema cure results were also statistically significant and consistent with the results of previous TP-03 studies. No statistically significant differences were observed between the BID and TID treatment arms and TP-03 was well tolerated.

“We are encouraged by these early results, which underscore the potential of TP-03 to address the underlying cause of disease,” said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. “We look forward to further analyzing the data from this trial and continued discussions with the U.S. Food and Drug Administration about the best path forward for TP-03 in MGD.”

About Meibomian Gland Disease
Meibomian Gland Disease (MGD) patients with *Demodex* mites often present with inflammation of the eyelid margin and blurred vision, which occurs when the meibomian glands are damaged and can result in blockage and/or decreased production of meibum liquid. If left untreated, MGD can lead to permanent changes to the tear film and progressive gland loss. Approximately 30-40 million Americans[5,6] have been diagnosed with MGD. Currently, there are no pharmacologic U.S. Food and Drug Administration (FDA) approved therapies for MGD.

About TP-03
TP-03 (lotilaner ophthalmic solution, 0.25%) is a novel therapeutic designed to treat *Demodex* blepharitis by targeting and eradicating the root cause of disease – *Demodex* mite infestation. It was approved by the FDA in 2023 under the brand name XDEMVY® for the treatment of *Demodex* blepharitis and is being evaluated as an investigational therapy for the treatment of Meibomian Gland Disease (MGD) in patients with *Demodex* mites. Lotilaner is a well-characterized anti-parasitic agent that paralyzes and eradicates *Demodex* mites by selectively inhibiting parasite-specific gamma-aminobutyric acid-gated chloride (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.

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 lives. The Titan study also showed that management tools prior to the approval of XDEMVY, such as tea tree oil and lid wipes, are ineffective at targeting the root cause of *Demodex* blepharitis.

About XDEMVY®
XDEMVY (lotilaner ophthalmic solution) 0.25%, formerly known as TP-03, is a novel prescription eye drop designed to treat *Demodex* blepharitis by targeting and eradicating the root cause of the disease – *Demodex* mite infestation. XDEMVY 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 the XDEMVY eye drop to be neutral to very comfortable. The most common ocular adverse reactions observed in the studies were instillation site stinging and burning which was reported in 10% of patients. Other ocular adverse reactions reported by less than 2% of patients were chalazion/hordeolum (stye) and punctate keratitis.

XDEMVY Indication and Important Safety Information

INDICATIONS AND USAGE
XDEMVY is indicated for the treatment of *Demodex* blepharitis.

Most common side effects: The most common side effect in clinical trials was stinging and burning in 10% of patients. Other side effects in less than 2% of patients were chalazion/hordeolum and punctate keratitis.

For additional information, please see full prescribing information available at: www.xdemvy.com.

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. XDEMVY (lotilaner ophthalmic solution) 0.25% is FDA approved in the United States for the treatment of *Demodex* blepharitis. Tarsus is also developing TP-03 as an investigational therapy for the treatment of Meibomian Gland Disease, which is currently being studied in a Phase 2a clinical trial. In addition, Tarsus is developing TP-04 for the potential treatment of Rosacea and TP-05, an oral tablet for the prevention of Lyme disease. TP-04 and TP-05 are both currently being studied in Phase 2a clinical trials to evaluate safety, tolerability, and proof-of activity.

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 with respect to MGD; the timing, objectives, and results of the clinical trials including the complete clinical results of the Ersa trial, anticipated regulatory and development milestones, our ability to continue investing in our business, 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, 2022 filed on March 17, 2023, the Form 10-Q for the quarter ended September 30, 2023 filed on November 9, 2023 with the SEC, 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.

References:

1. Korb DR, Blackie CA. Meibomian gland diagnostic expressibility: correlation with dry eye symptoms and gland location. Cornea. 2008;27(10):1142–1147. doi: 10.1097/ICO.0b013e3181814cffj. PMID: 19034129
2. Lane SS, et al. A new system, the LipiFlow, for the treatment of meibomian gland dysfunction. Cornea. 2012 Apr;31(4):396-404. doi: 10.1097/ICO.0b013e318239aaea. PMID: 22222996.
3. Tomlinson A, et al. The international workshop on meibomian gland dysfunction: report of the diagnosis subcommittee. Invest Ophthalmol Vis Sci. 2011 Mar 30;52(4):2006-49. doi: 10.1167/iovs.10-6997f. PMID: 21450918; PMCID: PMC3072162.
4. Bron AJ, Benjamin L, Snibson GR. Meibomian gland disease. Classification and grading of lid changes. Eye. 1991;5:395–411. DOI: 10.1038/eye.1991.65. PMID: 1743355.
5. Milner, MS, et al. Dysfunctional tear syndrome: dry eye disease and associated tear film disorders – new strategies for diagnosis and treatment. Current Opinion in Ophthalmology, 2017 Jan; 28 Suppl 1, 3–47. DOI: 10.1097/01.icu.0000512373.81749.b7. PMID: 28099212. PMCID: PMC5345890.
6. Foulks GN, Bran AJ. Meibomian gland dysfunction: a clinical scheme for description, diagnosis, classification, and grading. Ocul Surf. 2003;1:107-126. DOI: 10.1016/s1542-0124(12)70139-8. PMID: 17075643.

Media Contact:
Adrienne Kemp
Sr. Director, Corporate Communications
(949) 922-0801
AKemp@tarsusrx.com

Investor Contact:
David Nakasone
Head of Investor Relations
(949) 620-3223
DNakasone@tarsusrx.com