Tarsus Provides 2025 Update: Accelerating the Launch of XDEMVY® and Establishing Ocular Rosacea as the Next Category-Creating Opportunity in Eye Care

January 13, 2025

Advancing TP-04 (lotilaner ophthalmic gel) for the potential treatment of Ocular Rosacea, another large, underserved eye disease with no FDA-approved therapy; Initiation of Phase 2 study planned for 2H 2025

Management to host webcast on Tuesday, January 14, 2025, at 8:00 a.m. P.T. / 11:00 a.m. E.T.

IRVINE, Calif., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS) today provided an update on the Company's key priorities for 2025, including plans to advance TP-04 for the potential treatment of Ocular Rosacea, another category-creating opportunity in eye care.

"2024 was a groundbreaking year for Tarsus as we established XDEMVY as one of the most successful eye care launches to date. With consistent quarter-over-quarter revenue growth, rapid physician adoption, broad payer coverage to date, and continued acceleration in the number of bottles delivered to patients in the fourth quarter of 2024, our path to eye care leadership is clear," said Bobak Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. "I expect 2025 to be even more transformational as we turn up the dial on key strategic launch initiatives, plan to generate more new evidence highlighting the impact of XDEMVY and our pipeline candidates, and pursue Ocular Rosacea as the next potentially revolutionary opportunity in eye care."

XDEMVY (lotilaner ophthalmic solution, 0.25%) – Driving One of the Fastest Growing Categories in Eye Care

- During the first nine months of 2024, the Company delivered more than 104,000 bottles of XDEMVY to patients and generated more than $113 million in XDEMVY net product sales.
- By the end of Q3 2024, more than 13,000 Eye Care Professionals (ECPs) were prescribing XDEMVY with over 70% writing for multiple patients.
- Broad commercial and Medicare reimbursement now extends to more than 80% of lives covered and a gross-to-net discount percentage in the low 40s as of the end of Q3 2024.
- The deployment of approximately 50 new sales representatives and leaders in Q3 2024 started to deliver meaningful impact in Q4 2024.
- The Company initiated a trial run of its first direct-to-consumer advertising campaign on network TV in January 2025, including spots during the Golden Globes and National Football League (NFL) playoffs.
- Groundbreaking data from the Ersa and Rhea clinical trials for the treatment of *Demodex* blepharitis (DB) in patients with Meibomian Gland Disease (MGD) further underscore the utility of XDEMVY broadly across DB patient types.

Ocular Rosacea – Pursuing The Next Potentially Transformative Category in Eye Care

- Ocular Rosacea (OR) is a highly prevalent, undertreated eye disease with no FDA-approved therapy. It affects ~15-18 million Americans, and more than half of all cases are caused by an infestation of *Demodex* mites. This inflammatory condition affects the eyes and surrounding tissue and is often accompanied by the presence of prominent blood vessels, and redness across the eyes and eyelids.
- TP-04 is an investigational topical sterile ophthalmic gel formulation of lotilaner designed for application across the eyelid and surrounding tissue that represents a potentially category-creating therapy in an area of high unmet need.
    - Previous clinical trials of lotilaner in DB, MGD, and papulopustular rosacea demonstrated statistically significant improvements in key objective endpoint measures of disease.
    - Patent exclusivity expected to extend through 2038.
- Based on FDA feedback, the Company has established a clear regulatory path forward for TP-04 and plans to initiate a Phase 2 study in the second half of 2025. Results are anticipated in 2026.

Additional Potential Growth Drivers in 2025 and Beyond

- On-track for potential European regulatory approval of a preservative-free formulation of XDEMVY in 2027.

- In Japan, the Company expects to share results from an ongoing DB prevalence study in 2025 and meet with Japanese regulatory authorities to help determine a regulatory path forward.

- The Chinese regulatory agency, National Medical Products Administration, accepted the New Drug Application (NDA) submitted by Tarsus's partner, Grand Pharmaceutical Group Ltd., for TP-03 for DB. A decision is anticipated in 2027.

- The Company remains on-track to provide an update on TP-05 for the potential prevention of Lyme Disease by the FY 2024 earnings call.

Conference Call and Webcast
Tarsus will host a conference call and webcast on Tuesday, January 14, 2025, at 8:00 a.m. P.T. / 11:00 a.m. E.T. A live webcast will be available on the events section of the Tarsus website. A recorded version of the call will be available on the website shortly after the completion of the call and will be archived there for at least 90 days.

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: https://xdemvy.com/.

About TP-04
TP-04 is an investigational aqueous gel formulation of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills mites by selectively inhibiting parasite-specific GABA-Cl channels. Tarsus is studying TP-04 for the potential treatment of Ocular Rosacea (OR).

About TP-05
TP-05 is an investigational oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that selectively inhibits parasite-specific GABA-Cl channels. TP-05 is believed to be the only non-vaccine, drug-based, preventative therapeutic in development designed to kill ticks to potentially prevent Lyme disease transmission.

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 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-04 for the potential treatment of Ocular Rosacea and TP-05 as an oral tablet for the potential prevention of Lyme disease.

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 include statements regarding the potential commercial success and growth of XDEMVY in *Demodex* blepharitis, including market size, acceptance, demand, prescription fill rate and adoption rate for XDEMVY; our ability to successfully implement our sales force expansion and new direct-to-consumer campaign including network TV; our ability to achieve distribution and patient access for XDEMVY; our ability to continue to drive a successful launch of XDEMVY and become an eye care leader; our ability to continue to educate the market about *Demodex* blepharitis; anticipated regulatory and development milestones including potential regulatory pathways for approval of XDEMVY in Europe, China, and Japan; the market size and opportunity for our pipeline products including TP-04 for the potential treatment of Ocular Rosacea; the timing of initiation and results of our clinical studies including additional studies on the impact of XDEMVY, a Japan DB prevalence study, TP-04, and TP-05; the potential regulatory pathways and timing of discussions with regulators including the FDA; the impact of our new sales force representatives on our XDEMVY sales; 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. Further, there are other risks and uncertainties that could cause actual results to differ from those set forth in the forward-looking statements 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, 2023 filed on February 27, 2024 and the most recent Form 10-Q quarterly filing filed with the SEC filed on November 13, 2024, 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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