Now Available – XDEMVY™ (lotilaner ophthalmic solution) 0.25%, the First and Only FDA Approved Treatment for Demodex Blepharitis

August 24, 2023

Demodex blepharitis impacts approximately 25 million eye care patients in the U.S. – or 1 out of every 12 adults.

XDEMVY is indicated for all adult patients with Demodex blepharitis and is available via prescription from an eye care provider

Sales force deployed, calling on ophthalmologists and optometrists nationwide

IRVINE, Calif., Aug. 24, 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, starting with eye care, announced that XDEMVY™ (lotilaner ophthalmic solution) 0.25% is now available at pharmacies nationwide for prescription. The U.S. Food and Drug Administration (FDA) approved XDEMVY on July 24, 2023, for the treatment of *Demodex* blepharitis.

"We are delighted that within weeks of FDA approval, XDEMVY is now available to millions of patients with *Demodex* blepharitis," said Bobak Azamian, MD, PhD, Chief Executive Officer and Chairman of Tarsus. "The efforts of our team have created incredible interest in XDEMVY, the first and only approved solution for this highly prevalent disease. I'm so appreciative of our team and our partners who've worked diligently to bring this product to eye care providers and patients quickly and seamlessly following regulatory approval. We are proud to introduce XDEMVY to the eye care community and look forward to its potential to significantly change the way this disease is treated."

XDEMVY is the only FDA approved treatment to directly target *Demodex* mites, the root cause of *Demodex* blepharitis. *Demodex* blepharitis is characterized by redness, inflammation, missing or misdirected eyelashes, itching along the eyelid base, and the presence of collarettes. XDEMVY is a prescription eye drop that is administered with one drop in each eye twice daily (approximately 12 hours apart) for 6 weeks.

Tarsus is committed to ensuring that patients have affordable and broad access to XDEMVY and developed *Tarsus Connect*, a suite of assistance programs that provide financial support for eligible patients. More information about *Tarsus Connect* can be found on xdemvy.com or by calling: 1-866-846-3092.

To learn more about XDEMVY, including the Full Prescribing Information, please visit xdemvy.com and follow XDEMVY on Facebook and Instagram.

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* mite 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 current management tools, 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 for the treatment of *Demodex* blepharitis and is designed to target and eradicate the root cause of the disease – *Demodex* mite infestation. The active ingredient in XDEMVY is lotilaner, 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 eyelash follicles where the mites reside. 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 XDEMVY to be neutral to very comfortable. The most common ocular adverse reactions observed in the studies were 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.

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 three investigational medicines in clinical trials. In addition to XDEMVY (lotilaner ophthalmic solution) 0.25%, which is FDA approved in the United States for the treatment of *Demodex* blepharitis, Tarsus is also investigating TP-03 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.

XDEMVY Indication and Important Safety Information

Indications and Usage
XDEMVY (lotilaner ophthalmic solution) 0.25% is indicated for the treatment of *Demodex* blepharitis.

Important Safety Information
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.

Handling the Container: Avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to minimize contamination of the solution. Serious damage to the eye and subsequent loss of vision may result from using contaminated

solutions.

When to Seek Physician Advice: Immediately seek a physician's advice concerning the continued use of XDEMVY if you develop an intercurrent ocular condition (e.g., trauma or infection), have ocular surgery, or develop any ocular reactions, particularly conjunctivitis and eyelid reactions.

Use with Contact Lenses: XDEMVY contains potassium sorbate, which may discolor soft contact lenses. Contact lenses should be removed prior to instillation of XDEMVY and may be reinserted 15 minutes following its administration.

For additional information please see Full Prescribing Information available at: www.xdemvy.com.

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 availability of XDEMVY for prescription; potential market size for, interest in, and patient access to and affordability of XDEMVY; Tarsus' commercialization plans for and the anticipated benefits of XDEMVY; and the quotations of Tarsus' management and consultants/eye care providers. 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 and the most recent Form 10-Q quarterly filing filed with the SEC on August 10, 2023, 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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