Tarsus Initiates Phase 2a Ersa Trial Evaluating TP-03 for the Treatment of Meibomian Gland Disease

August 5, 2022

IRVINE, Calif., Aug. 05, 2022 (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, today announced that it has enrolled the first patient in a Phase 2a clinical trial studying TP-03 (lotilaner ophthalmic solution, 0.25%) for the treatment of Meibomian Gland Disease (MGD) in patients with *Demodex* mites. *Demodex* mites live in the meibomian glands and have been associated with microstructural glandular changes that can result in inflammation. Currently, there are no U.S. Food and Drug Administration (FDA) approved pharmacologic treatments for MGD. TP-03 has been evaluated in two pivotal trials collectively involving more than 800 patients with *Demodex* blepharitis where it met the primary endpoint and all secondary endpoints and was well-tolerated. Tarsus plans to submit a New Drug Application (NDA) to the FDA for TP-03 for the treatment of *Demodex* blepharitis in the second half of 2022.

“We’re enthusiastic about expanding our therapeutic footprint in eye care, as we evaluate TP-03 in another highly prevalent eyelid margin disease that has no FDA approved pharmacologic therapies,” said José Trevejo, M.D., Ph.D., Chief Medical Officer of Tarsus. “We look forward to leveraging key learnings from our Saturn-1 and 2 trials where TP-03 demonstrated statistically significant efficacy in treating *Demodex* blepharitis with a favorable safety profile. We are eager to explore its potential to treat another important eye disease associated with the presence of *Demodex* mites.”

The meibomian glands line the eyelid margin and are responsible for secreting lipids that make up the superficial lipid layer of the tear film and prevent tears from evaporating. MGD occurs when the glands are not producing enough lipids, or the lipids they secrete are of poor quality. MGD is highly prevalent and thought to be the leading cause of Dry Eye Disease, impacting approximately 2/3 of the 34 million patients with Dry Eye Disease in the U.S. Patients with MGD experience symptoms of eye irritation and inflammation and when left untreated, may experience permanent changes to the tear film and progressive gland loss.

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 anti-parasitic agent that paralyzes and 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. Both trials also demonstrated that TP-03 was generally safe and well-tolerated. 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 MGD 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 lives. 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. TP-03 is also being developed for the treatment of Meibomian Gland Disease. 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, 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 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.

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