# Tarsus Submits New Drug Application to the FDA for TP-03 for the Treatment of Demodex Blepharitis

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IRVINE, Calif., Sept. 07, 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 submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for TP-03 (lotilaner ophthalmic solution, 0.25%) for the treatment of *Demodex* blepharitis. *Demodex* blepharitis is a highly prevalent eyelid margin disease that does not have any FDA-approved treatment options. The NDA submission includes the positive results from the two pivotal trials (Saturn-1 and Saturn-2) collectively involving more than 800 patients in which TP-03 met all endpoints and was well-tolerated.

"TP-03 is the first and only investigational therapy to meet all endpoints in *Demodex* blepharitis pivotal trials. This NDA submission is a significant milestone for Tarsus and most importantly, it provides hope to millions of *Demodex* blepharitis patients who have been living with this damaging disease," said Bobby Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. "We are profoundly grateful to the hundreds of patients, dedicated eye care professionals and team members who contributed to this NDA and we look forward to working closely with the FDA to potentially bring TP-03 to patients."

**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. Both trials also demonstrated that TP-03 was well-tolerated. The most common adverse event occurring at a frequency of >2% in TP-03 treated patients was instillation site pain/burning/stinging; and all adverse events were either mild or moderate. 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 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 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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