Tarsus Pharmaceuticals, Inc. Initiates Saturn-2, Second Pivotal Phase 3 Trial Evaluating the Safety and Efficacy of TP-03 for the Treatment of Demodex Blepharitis

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Demodex blepharitis may affect up to 25 million Americans and result in significant clinical, functional and psychosocial burden for patients

Saturn-2 trial design similar to Saturn-1, first pivotal trial for TP-03

Topline data from Saturn-1 expected this July

IRVINE, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), a late clinical-stage biopharmaceutical company 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 commenced enrollment in Saturn-2, its second pivotal trial evaluating the company's novel investigational treatment, TP-03, in patients with Demodex blepharitis. Up to 25 million Americans may be affected by Demodex blepharitis, which is caused by an infestation of Demodex mites. TP-03 is a topical ophthalmic formulation of lotilaner, a well-characterized anti-parasitic agent designed to target and eradicate Demodex mites. Tarsus also recently completed full enrollment for the Saturn-1 pivotal trial, with 421 patients; topline results of the trial are expected to be announced this July.

Demodex blepharitis is a common, yet often overlooked or misdiagnosed, ocular disease that is characterized by inflammation of the eyelid margin, redness and ocular irritation. The disease is associated with significant clinical, functional and psychosocial burdens, with the recently presented Atlas study revealing that the majority of patients (80%) say the disease negatively affects their daily life. Currently, there is no FDA-approved therapy for the disease.

"We are pleased to complete first patient visits in Saturn-2, our second pivotal trial of TP-03 in Demodex blepharitis," said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. "Fully enrolling the Saturn-1 trial in a timely manner underscores patients' significant need for a safe and effective therapy, and we look forward to sharing the topline results this July. Demodex blepharitis can have a major impact on patients as evidenced by the Atlas study of participants pre-screened for Saturn-1. We are committed to progressing TP-03 with the goal of potentially providing the first FDA-approved drug treatment for this disease."

The Saturn-2 trial has a similar design to Saturn-1, and is a randomized, controlled, multicenter, double-masked trial studying the safety and efficacy of TP-03, lotilaner ophthalmic solution 0.25%, in adults with Demodex blepharitis. The trial's primary endpoint is the proportion of patients achieving collarette cure, defined as 0 to 2 eyelashes with collarettes. Secondary endpoints include the eradication of Demodex mites and the proportion of patients achieving a cure based on a composite of collarette cure and erythema cure (eyelid redness). We expect Saturn-2 to enroll approximately 418 participants who will administer TP-03 or vehicle twice daily for 42 days.

Tarsus has completed four Phase 2 clinical trials of TP-03 in Demodex blepharitis, all of which met their respective endpoints with no significant adverse events nor any events leading to treatment discontinuation. The positive results from these trials guided the design of the Saturn-1 and Saturn-2 pivotal trials. If the Saturn-1 and Saturn-2 trials are positive, we expect they will support the submission of a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) for TP-03 for the treatment of Demodex blepharitis.

About TP-03
TP-03 (lotilaner ophthalmic solution, 0.25%) is a novel, investigational therapeutic designed to target and eradicate Demodex mites. It is a potent, non-competitive antagonist of insect and arachnid GABA-Cl channels and a highly lipophilic molecule, which may promote its uptake in the oily sebum of the hair follicle where the mites reside. Tarsus has completed four Phase 2 clinical trials of TP-03 in Demodex blepharitis, all of which met their respective endpoints with no significant adverse events nor any events leading to treatment discontinuation. TP-03 is currently being evaluated in the Saturn-1 and Saturn-2 pivotal trials. If approved, TP-03 may offer treatment for millions of patients around the world with Demodex blepharitis.

About Demodex Blepharitis
Blepharitis is a common ocular condition that is characterized by inflammation of the eyelid margin, redness and ocular irritation. Demodex blepharitis is caused by infestation of Demodex mites, the most common ectoparasite found on humans. Demodex mites cause approximately 45% of blepharitis, or about 9 million cases in the US and the number may be as high as approximately 25 million based on Tarsus' internal research indicating about 58% of patients presenting to eye care clinics have collarettes, a pathognomonic sign of Demodex infestation, and a published study estimating that at least 45 million people annually visit an eye care clinic. Currently, there are no FDA-approved treatments for Demodex blepharitis.

About Tarsus Pharmaceuticals, Inc.
Tarsus Pharmaceuticals, Inc. is a late clinical-stage biopharmaceutical company that applies proven science and new technology to revolutionize treatment for patients, starting with eye care. It 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. Its lead product candidate, TP-03, is a novel therapeutic being studied in two pivotal trials for the treatment of Demodex blepharitis. TP-03 is also being developed for the treatment of Meibomian Gland 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 statements include statements regarding the market size for TP-03, enrollment expectations in the Saturn-2 trial, timing of topline data for Saturn-1, 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 and 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. Important factors that could cause actual results to differ materially from those in the forward-looking statements include: Tarsus has incurred significant losses and negative cash flows from operations since inception and anticipates that it will continue to incur significant expenses and losses for the foreseeable future; Tarsus may need to obtain additional funding to complete the development and any commercialization of its product candidates, if approved; Tarsus is heavily dependent on the success of its lead product candidate, TP-03 for the treatment of Demodex blepharitis; the COVID-19 pandemic may affect Tarsus' ability to initiate and complete preclinical studies and clinical trials, disrupt regulatory activities, disrupt manufacturing and supply chain or have other adverse effects on Tarsus' business and operations; even if TP-03 or any other product candidate that Tarsus develops receives marketing approval, Tarsus may not be successful in educating eye care physicians and the market about the need for treatments specifically for Demodex blepharitis and or other diseases or conditions targeted by Tarsus' products; the development and commercialization of Tarsus products is dependent on intellectual property it licenses from Elanco Tiergesundheit AG; Tarsus will need to develop and expand the company and Tarsus may encounter difficulties in managing its growth, which could disrupt its operations; the sizes of the market opportunity for Tarsus' product candidates, particularly TP-03 for the treatment of Demodex blepharitis and MGD, have not been established with precision and may be smaller than estimated; the results of Tarsus' earlier studies and trials may not be predictive of future results; any termination or suspension of, or delays in the commencement or completion of, Tarsus' planned clinical trials could result in increased costs, delay or limit its ability to generate revenue and adversely affect its commercial prospects; and if Tarsus is unable to obtain and maintain sufficient intellectual property protection for its product candidates, or if the scope of the intellectual property protection is not sufficiently broad, Tarsus' competitors could develop and commercialize products similar or identical to Tarsus' products. 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, 2020 filed with the SEC on March 31, 2021, 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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