Tarsus Pharmaceuticals, Inc. Presents Results of Pioneering Atlas Study at ARVO 2021 Annual Meeting Demonstrating the Functional and Psychosocial Impact of Demodex Blepharitis

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Demodex blepharitis is a common ocular condition that may affect up to 25 million Americans

Atlas study shows that Demodex blepharitis negatively impacts daily life for 80 percent of patients

Tarsus also presents complete efficacy and safety data from Phase 2b Europa trial, positive trial results used as the basis for the Saturn-1 & 2 pivotal trials

IRVINE, Calif., May 03, 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 data from its Demodex blepharitis clinical program presented at the virtual Association for Research in Vision and Ophthalmology (ARVO) 2021 Annual Meeting. Demodex blepharitis is a common ocular disease that may affect as many as 25 million Americans and has both clinical and psychosocial impacts. Characterized by inflammation of the eyelid margin, redness and ocular irritation, Demodex blepharitis is caused by an infestation of Demodex mites. Currently, there is no FDA-approved therapy for the disease. Tarsus' lead product candidate, TP-03, is a topical ophthalmic formulation of lotilaner, a well-characterized anti-parasitic agent, designed to target and eradicate Demodex mites, and is currently being evaluated in the pivotal Phase 2b/3 Saturn-1 trial.

Although highly prevalent, Demodex blepharitis is often overlooked or misdiagnosed and – as a result – patients may struggle with the condition for years. Until now, the psychosocial effects of Demodex blepharitis have been poorly characterized. The **Atlas study** is the first multi-center observational study to evaluate the functional and psychosocial impact of the disease, along with clinical manifestations, in adult patients. Overall, the study showed that Demodex blepharitis is associated with a significant symptomatic and psychosocial burden, negatively affecting daily life in the majority (80%) of patients with the disease.

"The results from the Atlas study are significant because they demonstrate that there are severe functional *and* psychosocial impacts related to Demodex blepharitis with regard to routine, everyday activities and overall quality of life," said Elizabeth Yeu, M.D., Chief Medical Advisor for Tarsus. "The study underscores the importance of identifying the disease sooner, as well as the need for a safe, effective therapy that may provide substantial relief to this patient population. Tarsus is committed to progressing their clinical program in this area to develop a therapy that may address the underlying cause of Demodex blepharitis."

The Atlas study surveyed 311 patients who were pre-screened at 8 sites participating in Tarsus' pivotal Phase 2b/3 Saturn-1 trial. Patients had three objective signs of Demodex blepharitis, including the presence of Demodex mites; presence of collarettes on the lashes, also known as cylindrical dandruff, which are a pathognomonic sign of Demodex blepharitis; and lid margin erythema. Patients were asked questions about ocular symptoms, diagnoses, and history and their questionnaire responses were analyzed. The study found that the functional and psychosocial burdens of Demodex blepharitis are considerable, leading patients to seek treatment and medical care, mostly unsuccessfully:

- More than half of patients (51%) said they had **signs and symptoms** of blepharitis for at least four years, but most (58%) reported they had never been diagnosed, even though a third had made at least two and sometimes more than six visits to a doctor seeking relief.
- Patients reported their **most bothersome symptoms** were itchy eyes and dry eyes, with the majority (52%) experiencing these symptoms frequently or all the time in the past month.
- Many patients said they were **emotionally affected**, with almost half (47%) conscious of their eyes all day, nearly a quarter (23%) constantly worrying about their eyes and 23% saying it gave their eyes or eyelids a negative appearance to others.
- The disease also affected their **daily activities**, with almost half (47%) reporting difficulty driving at night and nearly a third (30%) saying it added time to their daily hygiene routine.
- Most patients (81%) had **sought treatment**, but many of these patients discontinue treatment, citing ineffectiveness, tolerability, or other reasons.

"The Atlas study reveals the need for a proven treatment for Demodex blepharitis to treat patients' disease and end the daily toll it takes on their ocular health and quality of life," said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. "Our goal is to offer patients and eye care professionals the first drug treatment that targets the underlying cause of disease, and may positively impact the significant disease burden. We remain focused on advancing our pivotal TP-03 clinical program and we look forward to initiating Saturn-2 this quarter and announcing the results of Saturn-1 this summer."

Tarsus also presented the complete findings of the **Europa study**, a prospective, randomized, vehicle-controlled Phase 2b trial that evaluated the safety and efficacy of twice-daily TP-03, topical lotilaner ophthalmic solution 0.25%, in adult patients with Demodex blepharitis. Enrolled participants received no treatment for blepharitis symptoms (i.e., lid hygiene) during the study, as well as at least 14 days prior.

- In the trial, TP-03 demonstrated statistically significant results for the primary endpoint, collarette cure over vehicle, which was achieved in 80% of patients versus 16%, respectively, at 42 days ($p<0.001$).
- Furthermore, TP-03 demonstrated statistically significant results for the secondary endpoints. Mites were eradicated in 73%

of patients treated with TP-03 compared to 21% of the vehicle group (p=0.003) and composite collarette and erythema cure was achieved in 73% of patients treated with TP-03 compared to 11% of the vehicle group, both at 42 days (p<0.001).

- In post hoc analyses, 93% of patients treated with TP-03 had a clinically meaningful outcome of 10 or fewer lashes with collarettes by day 42.
- Additional post-hoc analyses showed that 87% of patients treated with TP-03 had mite density reduced by 50% or more by day 14.
- There were no serious adverse events and no discontinuations due to adverse events.

The positive results observed in the Europa study were used as the basis for the pivotal Phase 2b/3 Saturn-1 and Phase 3 Saturn-2 trials of TP-03 to treat 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 pivotal Phase 2b/3 trial. 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 in a pivotal Phase 2b/3 trial 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, 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 studies 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 physician 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 Tarsus' product. 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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