Tarsus Pharmaceuticals, Inc. Presents Data from Two Pioneering Studies on the Prevalence and Impact of Demodex Blepharitis at the American Academy of Optometry 2021 Annual Meeting

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Titan real-world prevalence study data reveals that Demodex blepharitis accounts for over two-thirds of all blepharitis cases and is highly prevalent in many commonly seen patient groups

New Titan study data analysis showed that current management tools, such as tea tree oil (TTO) and lid wipes, are ineffective at treating Demodex blepharitis

Atlas disease impact study showed that Demodex blepharitis is associated with a significant symptomatic and psychosocial burden, negatively affecting daily life in 80% of patients

IRVINE, Calif., Nov. 04, 2021 (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, presented data today from two pioneering studies on the prevalence and impact of Demodex blepharitis at the American Academy of Optometry (AAOpt) 2021 Annual Meeting in Boston, MA, the largest optometry meeting in the U.S. The Titan real-world prevalence study data revealed that Demodex blepharitis accounts for over two-thirds (69%) of all blepharitis cases and is present in many commonly seen patient groups. Additionally, new data revealed a high prevalence of collarettes in patient populations using TTO (75%) and lid wipes (57%), indicating that current management tools for this disease are largely ineffective. There are currently no U.S. Food and Drug Administration (FDA) approved therapeutics for Demodex blepharitis. Tarsus' lead investigational candidate, TP-03 (lotilaner ophthalmic solution, 0.25%), is currently being evaluated in the Saturn-2, Phase 3, pivotal trial for the treatment of Demodex blepharitis. TP-03 was previously evaluated in the Saturn-1, Phase 2b/3, pivotal trial involving 421 patients. Saturn-1 showed that TP-03 cleared the signs of Demodex blepharitis, met all primary and secondary endpoints with no serious treatment-related adverse events and was well-tolerated. Results from the Saturn-2, Phase 3, pivotal trial are anticipated in Q1 of 2022.

"Data from the Titan and Atlas studies provide optometrists with important insights into the prevalence and negative impact Demodex blepharitis can have on patients, as well as the limitations of current management tools," said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. "We know that optometrists are often on the frontlines of diagnosing this disease, as they are the first point of contact for many patients undergoing eye exams. We hope that sharing these findings will encourage them to continue to proactively identify the disease before it can have long-term negative impacts. These data also underscore the critical need for an effective solution for the treatment of this disease and we look forward to progressing the development of our of lead investigational candidate, TP-03, which – if FDA-approved – could become the standard of care for patients with Demodex blepharitis."

New Titan Study Data

The Titan study was an IRB-approved, retrospective chart review of 1,032 patients across six U.S.-based ophthalmology and optometry practices conducted by seven investigators. The study was designed to better understand the prevalence of Demodex blepharitis via collarettes in U.S. eye care clinics. Collarettes are a pathognomonic sign of Demodex blepharitis and are an accumulation of epithelial cells, keratin, mite waste product and eggs that form at the base of the eyelashes. The Titan study revealed that 58% of patients visiting eye care clinics for any reason had Demodex blepharitis, as evidenced by the presence of collarettes.

The new Titan data analysis demonstrates that Demodex blepharitis accounts for over two-thirds (69%) of all blepharitis cases and is present in many commonly seen patient populations. The new analysis showed a high collarette prevalence among eye care patients with glaucoma (65%), those taking a dry eye prescription treatment (60%), those with cataracts (56%) and among contact lens users (51%). The data also showed a high prevalence of collarettes among patients using TTO (75%) and lid wipes (57%) to manage their disease. These new data demonstrate that commonly used eye care treatments, even those used to manage blepharitis, are not effective at treating Demodex blepharitis.

"The Titan study demonstrates that Demodex blepharitis accounts for the majority of clinical blepharitis cases," said Paul Karpecki OD, FAAO, Director of Cornea Services at Kentucky Eye Institute in Lexington, KY and Associate Professor at the Kentucky College of Optometry in Pikeville, KY, and Titan study presenter. "Given the high collarette prevalence in many patient groups, it is important that all optometrists have patients look down during a standard slit lamp exam to check for the presence of collarettes on the eyelashes during each routine patient visit. I look forward to having a potential treatment option that can effectively provide relief for so many of my patients."

Atlas Study Data

The Atlas study was the first multi-center observational study to evaluate the impact of Demodex blepharitis. The study surveyed 311 patients who were pre-screened at eight sites participating in the pivotal Phase 2b/3 Saturn-1 trial evaluating the safety and efficacy of TP-03 in adults with Demodex blepharitis. Patients who had three objective signs of Demodex blepharitis, including the presence of Demodex mites, collarettes and lid margin redness, were asked questions about their ocular symptoms, diagnoses, and history, and their questionnaire responses were analyzed. The Atlas study showed that Demodex blepharitis is associated with a significant symptomatic and psychosocial burden, negatively affecting daily life in 80% of patients with the disease.

The study found that the considerable burdens of Demodex blepharitis led patients to seek treatment and medical care, mostly unsuccessfully:

- More than half of patients (51%) reported suffering from signs and symptoms of this disease for more than four years, having been to their eye doctor several times with no resolution, but most patients (58%) reported they had never been diagnosed with blepharitis.

- The most common symptoms reported were itchy eyes (55%) and dry eyes (46%).
- Many patients said they were emotionally affected – almost half (47%) reported being conscious of their eyes all day, nearly a quarter (23%) were constantly worried about their eyes and 23% said it gave their eyes or eyelids a negative appearance to others.
- The study also showed that the disease affected daily activities – almost half (47%) reported difficulty driving at night, nearly a third (30%) said it added time to their daily hygiene routine, and 34% of women reported difficulty wearing makeup.

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. TP-03 is a topical ophthalmic formulation of lotilaner, which is a well-characterized anti-parasitic agent that paralyzes and eradicates Demodex mites by selectively inhibiting parasite-specific GABA-Cl channels. 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. TP-03 was evaluated in the pivotal Saturn-1 (Phase 2b/3) trial involving 421 patients and met all primary and secondary endpoints with no serious treatment-related adverse events and was well tolerated. Prior to that, Tarsus also 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-2 (Phase 3) pivotal 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 an infestation of Demodex mites, the most common ectoparasite found on humans. 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 another published study estimating that at least 45 million people annually visit an eye care clinic. Demodex blepharitis can have a significant clinical burden and negatively impact patients' daily lives. 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. 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. The company is studying two investigational medicines in clinical trials. Its lead product candidate, TP-03, is a novel therapeutic being studied in a second Phase 3 pivotal trial for the treatment of Demodex blepharitis. TP-03 is also being developed for the treatment of Meibomian Gland Disease. Tarsus is developing TP-05, an oral, non-vaccine therapeutic for the prevention of Lyme disease, which is currently being studied in a Phase 1 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 Tarsus' plans for and the anticipating benefits of its product candidates, including TP-03 and TP-05, the timing, objectives and results of the clinical trials and anticipated regulatory and development milestones, including the timing of the Saturn-2 clinical trial and submission of an NDA, 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, TP-05, 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, Lyme disease, 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, as well as TP-05 for the treatment of Lyme disease, 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 and Form 10-Q for the quarter ended June 30, 2021 filed with the SEC on August 5, 2021, which Tarsus incorporates by reference into this press release and 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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