Tarsus Pharmaceuticals, Inc. Presents New Saturn-1 Pivotal Trial Data and Titan Real-World Prevalence Study Results at ASCRS 2021

July 24, 2021

New Saturn-1 data demonstrated a strong patient responder rate with 95% of Demodex blepharitis patients treated with TP-03 achieving ≤0.5 mites per lash and 93% improving by at least one collarette grade

Further Saturn-1 safety analysis revealed that TP-03 had a favorable safety profile with no clinically significant effect on multiple measures

Titan study reveals the high real-world prevalence of Demodex blepharitis, with collarettes present in 58% of U.S. patients visiting an eye doctor

IRVINE, Calif., July 24, 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 new data from its Saturn-1 Phase 2b/3 pivotal trial and the Titan real-world collarette prevalence study at the American Society of Cataract and Refractive Surgery (ASCRS) 2021 Annual Meeting. The new Saturn-1 data reinforce the strong potential clinical utility of TP-03 (lotilaner ophthalmic solution, 0.25%) for the treatment of Demodex blepharitis, with a broad range of patients showing a substantial response. The Titan study revealed the high prevalence of Demodex blepharitis in all-comer eye care patients in the U.S. across diverse populations and geographies, including significant overlap with some of the most commonly seen patients, such as those taking prescription dry eye treatments.

"We are very encouraged by the additional Saturn-1 data points, demonstrating that nearly all patients experienced a substantial response, and the clinical value that TP-03 may have for both patients and eye care professionals who have long struggled to manage Demodex blepharitis – a disease with no existing approved therapies," said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. "We have received a lot of enthusiasm and positive feedback on this new data from clinicians at the ASCRS meeting. The compelling results of the Saturn-1 trial mark an important step in our clinical program for TP-03 and bring us one step closer to the development of a much-needed therapy for patients suffering from this disease. Our second pivotal trial, Saturn-2 is currently enrolling. If the topline results expected in Q1 2022 are positive, we expect to submit a New Drug Application next year for TP-03 for the treatment of Demodex blepharitis."

Additional Saturn-1 Phase 2b/3 Results & Safety Data

New Saturn-1 data presented at ASCRS today, demonstrated that, in addition to achieving all primary and secondary endpoints, the results showed a strong patient responder rate, as nearly all Demodex blepharitis patients experienced a significant response to treatment with TP-03. These findings indicate the substantial potential impact this treatment may have for both patients and eye care professionals. Results showed meaningful improvement in the number of mites per lash as well as collarette grade reduction:

- 95% of TP-03 patients showed a significant response in mite count, achieving ≤0.5 mites per lash at day 43 from an average baseline of 3.2 mites per lash, compared to 36% of those on vehicle (p<0.0001), with statistically significant results seen as early as day 15.
- 93% of TP-03 patients improved by at least one collarette grade by day 43, from an average baseline of grade 2.8 or approximately 100 collarettes per lid, compared to 50% of those on vehicle (p<0.0001), with statistically significant results seen as early as day 8.

In addition to the data presented at the ASCRS meeting, Tarsus is also announcing results from additional Saturn-1 safety analysis, which revealed that TP-03 had no clinically significant effect on multiple safety measures including Corrected Distance Visual Acuity (CDVA), corneal staining, and intraocular pressure (IOP) and no significant findings from slit lamp biomicroscopy or fundus exam. In addition, no impact to endothelial cell density (ECD) was seen in a subset of 21 patients. ECD will be further evaluated as part of the Saturn-2 trial plan. Analysis from Saturn-1, along with previously announced data, reinforces that TP-03 is potentially safe to use in a broad patient population.

Saturn-1 (Phase 2b/3) was a randomized, controlled, multicenter, double-masked pivotal trial evaluating the safety and efficacy of TP-03 in adults with Demodex blepharitis. Previously announced Saturn-1 topline data showed that TP-03 met all its primary and secondary endpoints, including improvements in lid margin redness, with no serious treatment-related adverse events and no treatment-related discontinuations.

The Saturn-1 trial was the first pivotal large-scale trial to show positive, clinically meaningful and statistically significant patient improvements for a therapeutic specifically designed to treat Demodex blepharitis. TP-03 has the potential to be the first U.S. Food and Drug Administration (FDA)-approved therapeutic for Demodex blepharitis that targets the underlying cause of disease – Demodex mite infestation.

Tarsus is currently proceeding with the second pivotal trial, the Saturn-2 (Phase 3) trial, which has the same primary and secondary endpoints as Saturn-1 and is expected to report topline data results in Q1 2022.

Titan Study Results

The Titan study is an IRB-approved, retrospective chart review of 1,032 patients across six U.S.-based ophthalmology and optometry practices by seven investigators, designed to better understand the prevalence of collarettes in U.S. eye care clinics. Collarettes, or cylindrical dandruff, are a pathognomonic sign of Demodex blepharitis and are an accumulation of mite waste product and eggs that form at the base of the eyelashes. In data presented at ASCRS, the Titan study revealed the presence of collarettes in 58% (n=595) of patients. These results indicate a high prevalence of Demodex blepharitis across diverse patient populations and geographies. The study also revealed that the prevalence of Demodex blepharitis is similar to that of dry eye (58%, n=593).

“The Titan findings are significant and help to quantify how prevalent Demodex blepharitis is in real-life clinical practice, with more than half of observed patients presenting with collarettes,” said Ehsan Sadri, M.D., FACS, CEO and Founder of Visionary Eye Institute, Newport Beach and Titan study presenter at ASCRS. “The study also showed that collarettes are easy to identify through a close evaluation of the upper eyelid when patients are looking down during an eye exam. I look forward to the potential of a new, effective treatment option that can provide relief for this disease which impacts so many of my patients.”

The Titan study also found that most blepharitis patients (69%) had collarettes, underscoring the role that Demodex mites play in blepharitis cases. Additionally, 60% (n=135) of patients who were on a dry eye prescription also had collarettes. Analysis of these data suggest that these patients may have concomitant disease or that Demodex blepharitis may be the root cause or an exacerbating factor of their dry eye disease.

The Titan study findings are further supported by a prospective independent study presented at ARVO 2021 (Teo *et al*), which found that demodicosis was newly diagnosed in 55.3% of patients, with 61.8% and 68.3% noted to have blepharitis and dry eye, respectively.

Archived videos of the ASCRS presentations can be accessed via the following links:

- Safety and Efficacy of Topical Lotilaner, 0.25% for the Treatment of Demodex Blepharitis: Results of the Phase 2b/3 Saturn-1 Trial
- The Prevalence of Collarettes and Demodex Blepharitis in Ophthalmology and Optometry Practices

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 no treatment-related discontinuations. 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 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. 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. 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 includes statements regarding Tarsus’ plans for and the anticipating benefits of its product candidates, including TP-03, 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 March

31, 2021 filed with the SEC on May 11, 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.

Contacts:

Media Contact:
SuJin Oh
Shop PR
(917) 841-5213
sujin@shop-pr.com

Investor Contact:
Patti Bank
Westwicke Partners, an ICR company
(415) 513-1284
IR@tarsusrx.com