Tarsus Announces Positive Topline Data from Saturn-2 Phase 3, the Second Pivotal Trial of TP-03 for the Treatment of Demodex Blepharitis, and Expects to File a New Drug Application This Year

May 2, 2022

TP-03 met the primary and all secondary endpoints, effectively resolved Demodex blepharitis and was well-tolerated with no serious treatment-related adverse events

56% of patients on TP-03 achieved the primary endpoint of complete collarette cure

Webcast today at 8:00 a.m. ET to review Saturn-2 topline data

IRVINE, Calif., May 02, 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 TP-03 (lotilaner ophthalmic solution, 0.25%) met the primary endpoint and all secondary endpoints in the Saturn-2 pivotal Phase 3 trial with a favorable safety profile, reinforcing its ability to resolve *Demodex* blepharitis, a highly prevalent eyelid disease. With these positive results, Tarsus plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2022.

“The positive Saturn-2 data builds on the compelling results we observed in Saturn-1, demonstrating clear consistency in the safety, efficacy and strong clinical value proposition of TP-03. This milestone enables a first potential treatment for *Demodex* blepharitis and most importantly, provides hope to the millions of patients suffering from this disease,” said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. “As we direct our focus toward NDA filing and commercialization, we are one step closer to providing a solution to eye care professionals and patients that can resolve this disease. We are truly grateful to the many patients who participated in the trial and appreciate their time and commitment despite the challenges presented by the ongoing COVID-19 pandemic. We are also sincerely thankful for the investigators and our clinical team who skillfully drove the execution of this successful trial. We’re thrilled to move the regulatory path forward for TP-03, which – if approved by the FDA – will potentially establish a definitive standard of care for *Demodex* blepharitis and benefit as many as 25 million U.S. patients in need.”

“The high statistical significance and clinically meaningful outcomes in Saturn-2 and Saturn-1 demonstrate the impressive ability of TP-03 to resolve *Demodex* blepharitis, a disease that has long been without an effective, safe treatment option,” said Elizabeth Yeu, M.D., Director and Chief Medical Advisor for Tarsus. “We know that this disease has a significant impact on patients’ vision and their daily life, and that they often struggle for years without relief. I am thrilled at the prospect of having TP-03 potentially available in the near future.”

Saturn-2 Topline Results

Saturn-2 is a Phase 3 randomized, controlled, double-masked trial evaluating the efficacy and safety of TP-03 in patients with *Demodex* blepharitis. The trial enrolled 412 adults having more than 10 collarettes per lid and at least mild lid erythema (redness). Each patient also had at least 1.5 mites per lash. One drop of TP-03 was self-administered twice per day in each eye for six weeks. Enrolled patients received no treatment for blepharitis (e.g., lid hygiene) during the trial or 14 days prior to enrollment. Key topline results:

- **Primary endpoint:** Complete collarette cure, defined as 0 to 2 collarettes per lid at day 43, was achieved by 56% of patients on TP-03, compared to 13% on vehicle (p<0.0001).
    - Additionally, 89% of patients achieved a significant, clinically meaningful collarette cure defined by a collarette grade of zero (0) or one (1) at day 43 compared to 33% of those on vehicle (p<0.0001).
- **Secondary endpoints:**
    - **Mite eradication**: Defined as a mite density of zero (0) mites per lash, was achieved by 52% of patients on TP-03 compared to 14% on vehicle (p<0.0001) at day 43.
    - **Complete lid erythema (redness) cure:** 31.1% of patients on TP-03 compared to 9.0% of patients on vehicle (p<0.0001) achieved a complete lid erythema cure at day 43.
    - **Complete composite cure:** 19.2% of patients on TP-03 achieved a complete composite cure, based on achieving both collarette cure and erythema cure, compared to 4.0% on vehicle (p<0.0001) at day 43.
- **Safety Profile:** Consistent with Saturn-1, Saturn-2 trial results demonstrated that TP-03 was well-tolerated with a safety profile similar to the vehicle group.
    - 91% of patients reported that the drop comfort was neutral to very comfortable.
    - There were no serious treatment-related adverse events. The only adverse events occurring at a rate of ≥1% in the TP-03 group were instillation site pain/burning/stinging (7.9%, n=16) and dry eye (1.5%, n=3).

Webcast Information

Tarsus will host a webcast to discuss the results from the Saturn-2 Phase 3 trial today, May 2nd at 8:00 a.m. ET. The webcast can be accessed on the events section of the Tarsus website. After the live webcast, the event will remain archived on the Tarsus website at https://ir.tarsusrx.com/ for 90 days.

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 anti-parasitic agent that paralyzes and 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 hair follicle where the mites reside. TP-03 was evaluated in two pivotal trials collectively involving 833 patients. Both trials met the

primary and all secondary endpoints, with statistical significance and no serious treatment-related adverse events. Both trials also demonstrated that TP-03 was generally safe and well-tolerated. If approved, TP-03 may offer treatment for millions of patients with *Demodex* blepharitis.

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 negatively impact 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, 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, the Company's cash balance at March 31, 2022 and the quotations of Tarsus' management and board members. 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 with the SEC, 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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