Tarsus Completes Enrollment for the Pivotal Phase 3 Saturn-2 Trial of TP-03 to Treat Demodex Blepharitis and Secures $175 Million Credit Facility

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Topline data expected in April 2022 from Saturn-2, the second Phase 3 pivotal trial of TP-03 and NDA submission remains on track for this year

Credit facility with Hercules Capital and Silicon Valley Bank provides availability of non-dilutive capital

IRVINE, Calif., Feb. 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 it has completed enrollment of Saturn-2, the company's second pivotal Phase 3 trial of TP-03 (lotilaner ophthalmic solution, 0.25%) for patients with Demodex blepharitis and executed a $175 million credit facility with Hercules Capital, Inc. (NYSE: HTGC) and Silicon Valley Bank (NASDAQ: SIVB).

Saturn-2 Enrollment Completion
"We are delighted Saturn-2 has completed enrollment with 408 patients during these challenging times, which speaks to the urgent need for an effective treatment for people living with Demodex blepharitis. We are committed to developing a solution for this disease as rapidly as possible and expect to share topline results from Saturn-2 in April, which, if positive, will be followed by a New Drug Application for TP-03 planned this year," said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus.

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 primary endpoint is the proportion of patients achieving complete collarette cure, defined as 0 to 2 collarettes per lid and secondary endpoints are mite eradication, lid margin erythema (redness) cure and a composite of collarette and erythema cures. Saturn-2 has similar powering assumptions and design to the completed pivotal Saturn-1 trial, which successfully met the primary and all secondary endpoints. Tarsus expects topline results for the Saturn-2 trial in April and if the results are positive, data from both the Saturn-1 and Saturn-2 trials will support submission of a New Drug Application (NDA) for TP-03 for the treatment of Demodex blepharitis planned for later this year.

Credit Facility with Hercules Capital and Silicon Valley Bank
"We are also grateful to secure this non-dilutive $175 million credit facility, providing Tarsus with significant financial flexibility to drive our business growth as we continue to pioneer the treatment landscape for patients with Demodex blepharitis and other important diseases," said Dr. Azamian. "With these developments, we are on track to advance and expand our pipeline, including delivering pivotal Phase 3 data from Saturn-2, submitting the TP-03 NDA for Demodex blepharitis, and if approved, be well-positioned for our expected commercial launch of TP-03 next year."

"Hercules is proud to partner with Tarsus ahead of several important milestones in the advancement of TP-03 and other programs. This is a significant commitment given our excitement around the positive clinical evidence and the potential for TP-03 to improve the treatment paradigm for patients with Demodex blepharitis," said Himani Bhalla, Managing Director at Hercules Capital.

"The team at Silicon Valley Bank is happy to work with Tarsus' leadership team to provide this facility and support the important work they are doing to revolutionize treatments for patients with Demodex blepharitis," said Michael White, Managing Director, Business Development, Life Sciences & Healthcare at Silicon Valley Bank.

Availability under this credit facility potentially extends cash runway well into the anticipated commercialization of TP-03. The $175 million is available as follows: $40 million at closing with $20 million drawn, $25 million at TP-03 NDA submission, $35 million at TP-03 FDA approval, and $75 million upon achievement of certain revenue thresholds and other conditions. The interest-only period is four years and is extendable to five years upon meeting certain conditions. Future draws are at Tarsus' election and there is no warrant coverage to the lenders.

Additional details of the credit facility agreement are filed with the Securities and Exchange Commission on a Current Report on Form 8-K.

Armentum Partners served as Tarsus' financial advisor in connection with this credit facility.

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 the pivotal Saturn-1 (Phase 2b/3) trial involving 421 patients and successfully met the primary and secondary endpoints with no serious treatment-related adverse events and was well tolerated. TP-03 is currently being evaluated in the Saturn-2 (Phase 3) pivotal trial. If approved, TP-03 may potentially offer treatment for millions of patients around the world 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. 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 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 market size for TP-03 and TP-05, future events and Tarsus’ plans for and the anticipated benefits of its product candidates including TP-03, TP-04 and TP-05, the timing, objectives and results of the clinical trials, anticipated regulatory and development milestones, future financial condition and position, 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 and 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 on March 31, 2021 and the most recent Form 10-Q quarterly filing for the quarter ending September 30, 2021 filed on November 10, 2021 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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