Tarsus Pharmaceuticals, Inc. Announces Type C Meeting with FDA Regarding NDA Submission Requirements for Lead Candidate TP-03

December 23, 2020

The Company began enrolling patients in Saturn-1 in September 2020 and expects to initiate its second pivotal registration trial, Saturn-2, in 2021

IRVINE, Calif., Dec. 23, 2020 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), a late clinical-stage biopharmaceutical company whose mission is to discover and deliver breakthrough treatments to transform the lives of patients with common and poorly treated diseases, starting with the eye, today announced that it received written minutes from the (Type C) meeting held on December 8 with the United States Food and Drug Administration (FDA). The meeting was held to align on specific NDA submission requirements for TP-03, a novel therapeutic in development for the treatment of Demodex blepharitis, and the Company believes it received collaborative and productive guidance.

“Recently, we held a productive Type C meeting with the FDA. At this meeting, we obtained valuable feedback on the data requirements for an NDA filing consistent with our existing plans: specifically, regarding the non-clinical toxicology, clinical and CMC components,” said Sesha Neervannan, COO of Tarsus. “We are pleased to continue advancing TP-03 through its pivotal trials and towards a potential NDA filing in order to provide the more than 9 million people in the United States that suffer from Demodex blepharitis a potential therapeutic treatment option.”

Recently, Tarsus completed its Io and Europa Phase 2 clinical trials, and began enrolling patients in Saturn-1, its Phase 2b/3 pivotal trial. The company plans to initiate its second pivotal registration trial, Saturn-2, in 2021, and expects for the data to support the potential submission of an NDA for TP-03 to treat Demodex blepharitis. TP-03 has the potential to be the first FDA-approved therapeutic and standard of care for the treatment of Demodex blepharitis.

About TP-03
TP-03 (lotilaner ophthalmic solution 0.25%) is a novel 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. TP-03 has completed four Phase 2 clinical trials in Demodex blepharitis, all of which met their respective endpoints. It was well-tolerated with no significant adverse events nor any events leading to treatment discontinuation across the four trials. TP-03 is currently being evaluated in the Saturn-1 pivotal Phase 2b/3 trial and may offer treatment, if approved, for millions of patients 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%, or about 9 million, of blepharitis 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 whose mission is to discover and deliver breakthrough treatments to transform the lives of patients with common and poorly treated diseases, starting with the eye. It is advancing its pipeline to address several diseases across therapeutic categories including eye care, dermatology, and other diseases with high, unmet needs. Its lead product candidate, TP-03, is a novel therapeutic in Phase 2b/3 that is being developed for the treatment of Demodex blepharitis.

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 future events and Tarsus’ plans for and the anticipated benefits of its product candidates, the timing, objectives and results of the clinical studies and anticipated regulatory and development milestones. 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, 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.

Media Contact:
Allison Howell
Pascale Communications, LLC
allison@pascalecommunications.com

Investor Contact:
Patti Bank
Westwicke Partners, an ICR company

(415) 513-1284
IR@tarsusrx.com