Tarsus Doses First Participant in Calliope, A Phase 2 Clinical Trial of TP-05 (lotilaner), a Novel Investigational Oral Tablet for the Potential Prevention of Lyme Disease

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– A pioneering investigational oral prophylactic approach designed to kill Lyme-infected ticks before disease transmission –

IRVINE, Calif., March 31, 2026 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS) today announced that the first participant has been dosed in the Phase 2 clinical trial (Calliope) evaluating TP-05 (lotilaner), a novel investigational oral therapy designed to potentially prevent Lyme disease by killing Lyme-infected ticks before disease transmission occurs.

Calliope is a randomized, double-blind, placebo-controlled Phase 2 trial evaluating the safety, tolerability and pharmacokinetics of orally administered TP-05 in approximately 700 healthy adults at risk for Lyme disease across endemic regions of the United States. Tarsus plans to complete enrollment during the 2026 tick season, with topline results expected in the first half of 2027.

“For decades, Lyme disease management has focused on treating infection after it occurs,” said Bobby Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. “We believe there is an opportunity to fundamentally shift that paradigm toward prevention by targeting the ticks that transmit the disease. The Calliope trial represents an important step in developing what could potentially be the first FDA-approved on-demand oral prophylactic option designed to help prevent Lyme disease.”

“With climate change and the expanding geographic range of ticks infected with human pathogens contributing to a growing burden of tick-borne illnesses, Lyme disease is becoming an increasingly urgent public health challenge,” said Linden Hu, M.D., the Paul and Elaine Chervinsky Professor of Immunology at Tufts University School of Medicine. “Tick bites and early symptoms are often missed, leading to missed diagnoses or delayed treatment, increasing the risk of serious long-term complications. New prophylactic approaches with the potential to help reduce the risk of infection could play an important role in addressing this growing threat.”

There are currently no U.S. Food and Drug Administration (FDA)-approved pharmacological prophylactic options for Lyme disease, the most common vector-borne disease in the United States. Lyme disease is caused by *Borrelia burgdorferi* infection and transmitted through the bite of infected ticks. According to recent market research, more than 35 million Americans are considered to be at moderate to high risk of contracting Lyme disease, and an estimated 300,000 – 400,000 people are diagnosed annually.

The Calliope trial design was informed by the Phase 2a Carpo randomized, double-blind, placebo-controlled, proof-of-concept “tick kill” study, in which a single dose of TP-05 demonstrated statistically significant tick mortality versus placebo at both Day 1 and Day 30. Tick kill rates exceeded 90% within 24 hours of attachment after the Day 1 tick challenge compared to only 5% for placebo ($p<0.001$), and TP-05 was generally well tolerated. Preclinical pilot studies in mice evaluating TP-05 for the prevention of Lyme disease also demonstrated 90% efficacy versus 0% in control mice.

About TP-05
TP-05 is an investigational oral systemic formulation of lotilaner. It is believed to be the only non-vaccine, drug-based prophylactic in development designed to kill ticks to potentially prevent Lyme disease transmission.

About Lyme Disease
Lyme disease is the most common vector-borne disease in the United States, transmitted to humans by *Borrelia burgdorferi* infection following the bite of a tick vector. According to recent market research, more than 35 million Americans are considered to be at high or moderate risk of contracting Lyme disease, and approximately 300,000 – 400,000 people in the U.S. are diagnosed and treated each year. Early signs of Lyme disease are often overlooked or misdiagnosed. Left untreated, Lyme disease can potentially cause severe, often debilitating symptoms with permanent and irreversible damage. The disease can result in inflammation, nerve, joint and muscle pain and swelling, numbness, shortness of breath and – in severe cases – neurological complications such as facial palsy, vision issues and meningitis, including severe headaches and neck stiffness, as well as cardiac complications. Data from the Centers for Disease Control and Prevention (CDC) show that the risk of Lyme disease is spreading to new geographical areas, resulting in a significant need for prophylactic solutions. Currently, there are no FDA-approved pharmacological prophylactic options for Lyme disease.

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. XDEMVY® (lotilaner ophthalmic solution) 0.25% is FDA approved in the United States for the treatment of *Demodex* blepharitis. Tarsus is also developing TP-04 for the potential treatment of ocular rosacea and TP-05 as an oral tablet for the potential prevention of Lyme disease, both of which are in Phase 2.

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 our ability to execute clinical studies including the Phase 2 Calliope trial for the potential prevention of Lyme disease, the time frame for results of our clinical studies, and the quotations of Tarsus’ management and advisors. 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. Further, there are other risks and uncertainties that could cause actual results to differ from those set forth in the forward-looking statements 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, 2025 filed on February 23, 2026, 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, except as required by law.

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