Tarsus Announces Positive Topline Data from Phase 1b Callisto Trial and Initiates Phase 2a Carpo Human Tick Kill Trial Evaluating TP-05, A Novel, Oral Therapeutic for the Prevention of Lyme Disease

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Positive Phase 1b Callisto data shows that TP-05 is well tolerated and safety data supports progression to Phase 2a

Phase 2a Carpo trial to evaluate the safety, tolerability, and proof-of-activity of TP-05 in healthy subjects

TP-05 designed to be an on-demand, long-acting prophylactic treatment that targets and eradicates ticks that transmit Lyme disease

IRVINE, Calif., Dec. 15, 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 positive topline results from the completed Phase 1b Callisto trial and the enrollment of the first subject in the Carpo Phase 2a trial. The Callisto and Carpo trials are designed to evaluate TP-05, a novel investigative oral therapeutic for the potential prevention of Lyme disease.

The Callisto trial was a randomized, double-blind, single- and multiple-ascending dose study that evaluated the safety, tolerability, food-effect, and pharmacokinetics (PK) of TP-05 in healthy subjects. Results from the trial showed that TP-05 was well tolerated with no dose-related or drug-related serious adverse events. Pharmacokinetic data from the trial demonstrated rapid absorption and an extended half-life of TP-05 that potentially supports a monthly, or less frequent therapy regimen, supporting its potential as a convenient, rapid onset, prophylactic therapy for Lyme disease. Additionally, exploratory ex-vivo tick kill modeling utilizing serum from TP-05-treated subjects demonstrated potent, rapid killing of adult and nymph ticks.

Tarsus also announced the enrollment of the first patient in the Carpo trial, evaluating TP-05 for the potential prevention of Lyme disease in humans. The Carpo trial is a randomized, double-blind trial that will evaluate the efficacy of TP-05 in killing sterile, non-disease carrying ticks after they have attached to the skin of healthy volunteers, as well as confirm the safety, tolerability, and blood concentration of TP-05.

TP-05 is an oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that selectively inhibits parasite-specific GABA-CI channels. TP-05 is believed to be the only non-vaccine, drug-based, preventative therapeutic in development designed to kill ticks to potentially prevent Lyme disease transmission.

“Lyme disease is a growing global health concern that may result in serious, often irreversible sequelae if left untreated,” said José Trevejo, MD, PhD, Chief Medical Officer of Tarsus. “As the risk of infection extends into new regions and as overall prevalence grows, identifying a solution to prevent transmission becomes paramount. Tarsus is committed to addressing large, underserved disease areas with unique solutions and our TP-05 investigational program embodies this commitment, as there are no current preventative options for this important disease.”

There are currently no U.S. Food and Drug Administration (FDA)-approved pharmacological prophylactic options for Lyme disease, which is the most common vector-borne disease in the United States. Lyme disease is transmitted through *Borrelia burgdorferi* infection following the bite of a tick vector. Over 30 million Americans are at high or moderate risk of contracting Lyme disease and there are approximately 300,000 – 400,000 cases in the U.S. each year.

About TP-05
TP-05 is an oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills ticks that transmit Lyme disease by selectively inhibiting parasite-specific GABA-CI channels. Tarsus is studying TP-05 for the prevention of Lyme disease and has completed a Phase 1b single ascending dose and multiple ascending dose (SAD/MAD) trial to evaluate the safety, tolerability and pharmacokinetics (PK) of TP-05 in healthy volunteers. TP-05 is currently being studied in a Phase 2a clinical trial to evaluate its safety, tolerability, and proof-of-activity. In addition to Lyme disease, Tarsus is also exploring the application of TP-05 for prevention of malaria transmission within an endemic population.

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. Over 30 million Americans are at high or moderate risk of contracting Lyme disease and there are approximately 300,000 – 400,000 cases in the U.S. each year. 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. Lyme disease can often go undetected and untreated because the ticks are not always noticed before they transmit the disease. People who spend extended amounts of time outdoors in wooded, grassy areas are at higher risk of Lyme disease. 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. 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, and the New Drug Application has been accepted by the U.S. Food & Drug Administration (FDA) with a PDUFA target action date of August 25, 2023. TP-03 is also being developed for the treatment of Meibomian Gland Disease, and currently being studied in a Phase 2a clinical trial. 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 2a clinical trial to evaluate its safety, tolerability, and proof-of-activity.

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 approval and commercialization of TP-03 and TP-05, the potential market size for TP-05, future events and Tarsus’ plans for and the anticipated benefits of its product candidates including TP-03 and TP-05, the timing, objectives and results of the clinical trials including the potential complete clinical results of the Callisto trial and continued enrollment and completion of the Carpo trial, anticipated regulatory and development approvals and milestones, 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. 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 and the most recent Form 10-Q quarterly filing filed 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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