Tarsus Pharmaceuticals, Inc. Initiates Phase 1 Callisto Trial of TP-05, a Novel, Oral, Non-Vaccine Therapeutic for the Prevention of Lyme Disease

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More than 30 million Americans at risk for Lyme disease exposure, which can result in severe neurological and other debilitating symptoms

First participants dosed in single ascending dose and multiple ascending dose (SAD/MAD) trial to evaluate safety, tolerability and pharmacokinetics of TP-05 in healthy volunteers

TP-05 is designed to kill infected ticks attached to the human body before they can transmit the Borrelia bacteria that causes Lyme disease

IRVINE, Calif., June 16, 2021 (GLOBE NEWSWIRE) -- Tarsus Pharmaceuticals, Inc. (NASDAQ: TARS), a late clinical-stage biopharmaceutical company 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 it has initiated dosing participants in its first clinical trial for TP-05, a novel, oral, non-vaccine therapeutic for the prevention of Lyme disease. The Phase 1 Callisto trial is a single ascending dose and multiple ascending dose trial to evaluate the safety, tolerability and pharmacokinetics (PK) of TP-05 in healthy volunteers. 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, transmitted to humans through the infection of the bacterium *Borrelia burgdorferi* following the bite of a tick vector.

TP-05 is an oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills ticks by selectively inhibiting parasite-specific GABA-Cl channels. TP-05 is believed to be the only non-vaccine, drug-based, preventive therapeutic in development that targets the ticks, and potentially prevents disease transmission. It is designed to rapidly provide systemic blood levels of lotilaner and kill infected ticks attached to the human body before they can transmit the *Borrelia* bacteria that causes Lyme disease.

“Millions of Americans are at high or moderate risk of contracting Lyme disease, which can lead to significant and long-term health problems. There is a great need for a preventive solution that has the potential to kill the tick before it transmits disease,” said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. “Initiating the TP-05 Phase 1 Callisto trial is an important step toward potentially offering a fast-onset and long-acting, oral, non-vaccine therapeutic to help protect those who are at risk for this potentially devastating disease.”

The Callisto trial intends to enroll healthy volunteers and evaluate a wide range of doses of TP-05 in the single dose phase. The multiple dose phase is planned to evaluate different doses of TP-05, each dosed periodically, and determined based on the single dose phase data. In addition to safety assessment, the systemic PK profile of TP-05, including blood levels and epidermal levels, will be assessed to provide valuable information to design future clinical studies and help facilitate exploratory research. The results of this Phase 1 trial are also expected to inform future work on TP-05 for malaria prevention.

“We are evaluating a broad range of doses in this trial to identify the optimal dose to progress to the next phase of research as quickly as possible,” said Sesha Neervannan, Ph.D., Chief Operating Officer of Tarsus. “Advancing TP-05, our second investigational product, to the clinical phase of development is a significant milestone for Tarsus and represents our commitment to address high unmet needs by applying proven science and new technology to revolutionize treatment for patients.”

Lyme disease can 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 symptoms, 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. Furthermore, symptoms of the disease are diverse and often incorrectly attributed to other conditions. 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.

About TP-05
TP-05 is an oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills parasites by selectively inhibiting parasite-specific GABA-Cl channels. Tarsus is studying TP-05 for the prevention of Lyme disease and has initiated a Phase 1 single ascending dose and multiple ascending dose (SAD/MAD) trial to evaluate the safety, tolerability and pharmacokinetics (PK) of TP-05 in healthy volunteers. In addition to Lyme disease, Tarsus is also exploring TP-05 for potential community malaria reduction.

About Lyme Disease
Lyme disease is the most common vector-borne disease in the United States, transmitted to humans by infection of *Borrelia burgdorferi* 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. People who spend extended amounts of time outdoors in wooded, grassy areas are at higher risk of getting the infection. 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. is a late clinical-stage biopharmaceutical company that 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 two pivotal trials 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 1 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 and TP-05, the timing, objectives and results of the clinical trials and anticipated regulatory and development 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. Important factors that could cause actual results to differ materially from those in the forward-looking statements include: Tarsus has incurred significant losses and negative cash flows from operations since inception and anticipates that it will continue to incur significant expenses and losses for the foreseeable future; Tarsus may need to obtain additional funding to complete the development and any commercialization of its product candidates, if approved; Tarsus is heavily dependent on the success of its lead product candidate, TP-03 for the treatment of Demodex blepharitis; the COVID-19 pandemic may affect Tarsus' ability to initiate and complete preclinical studies and clinical trials, disrupt regulatory activities, disrupt manufacturing and supply chain or have other adverse effects on Tarsus' business and operations; even if TP-03, TP-05 or any other product candidate that Tarsus develops receives marketing approval, Tarsus may not be successful in educating physicians and the market about the need for treatments specifically for Demodex blepharitis, Lyme disease or other diseases or conditions targeted by Tarsus' products; the development and commercialization of Tarsus products is dependent on intellectual property it licenses from Elanco Tiergesundheit AG; Tarsus will need to develop and expand the company and Tarsus may encounter difficulties in managing its growth, which could disrupt its operations; the sizes of the market opportunity for Tarsus' product candidates, particularly TP-03 for the treatment of Demodex blepharitis and MGD, as well as TP-05 for the treatment of Lyme disease, have not been established with precision and may be smaller than estimated; the results of Tarsus' earlier studies and trials may not be predictive of future results; any termination or suspension of, or delays in the commencement or completion of, Tarsus' planned clinical trials could result in increased costs, delay or limit its ability to generate revenue and adversely affect its commercial prospects; and if Tarsus is unable to obtain and maintain sufficient intellectual property protection for its product candidates, or if the scope of the intellectual property protection is not sufficiently broad, Tarsus' competitors could develop and commercialize products similar or identical to Tarsus' product. 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, 2020 filed with the SEC on March 31, 2021 and Form 10-Q for the quarter ended March 31, 2021 filed with the SEC on May 11, 2021, 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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