Tarsus Pharmaceuticals, Inc. Announces FDA Acceptance of Investigational New Drug Application for TP-05 for Lyme Disease Prevention

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Novel candidate in development aims to be first approved non-vaccine therapeutic for Lyme disease prevention

Allows initiation of Phase 1 study to evaluate safety, pharmacokinetics, and dosing

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

IRVINE, Calif., May 04, 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 the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application for TP-05, an oral, non-vaccine therapeutic for the prevention of Lyme disease. With this IND acceptance, Tarsus will initiate a Phase 1 single ascending dose and multiple ascending dose (SAD/MAD) study to evaluate the safety, tolerability, and pharmacokinetics (PK) of TP-05 in healthy volunteers. Study initiation is anticipated in July.

"We are pleased that the FDA has accepted the IND for TP-05, which is an important milestone in our pipeline development. Currently, there are no approved pharmacological prophylactic options for tick kill and preventing transmission of Lyme disease, which has the potential to cause severe, often debilitating symptoms with permanent and irreversible damage," said Bobak Azamian, M.D., Ph.D., President and Chief Executive Officer of Tarsus. "There is a significant unmet need for a therapeutic to quickly and reliably prevent this disease that can lead to poor outcomes for so many people. We look forward to initiating our clinical development program for TP-05 and advancing the path for this much-needed therapeutic for Lyme disease prevention."

Lyme disease is transmitted to humans after the bite of a blacklegged tick infected with the *Borrelia* bacteria. It is the most common vector-borne disease in the United States and 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 impacts more than 300,000 people in the U.S. each year and over 30 million are at high or moderate risk for contracting the disease.

TP-05 is an oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills ticks by blocking the parasite-specific GABA-CI channels. TP-05 is believed to be the only non-vaccine based therapeutic in development and 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. In addition to the prevention of Lyme disease, Tarsus is also exploring TP-05 for the community prevention of malaria.

Tarsus is currently conducting a pivotal trial evaluating the efficacy and safety of TP-03, a topical ophthalmic formulation of lotilaner, for the treatment of Demodex blepharitis, a common ocular condition caused by an infestation of Demodex mites.

About TP-05
TP-05 is an oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that paralyzes and kills parasites by inhibiting parasite-specific GABA-Cl channels. Tarsus is studying TP-05 for the prevention of Lyme disease. In July of 2021, Tarsus will initiate a Phase 1 single ascending dose and multiple ascending dose (SAD/MAD) study 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 the community prevention of malaria.

About Lyme Disease
Lyme disease is the most common vector-borne disease in the United States, transmitted to humans after the bite of a blacklegged tick infected by the bacterium *Borrelia burgdorferi.* 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 (CDC) shows 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. Its lead product candidate, TP-03, is a novel therapeutic in a pivotal Phase 2b/3 trial for the treatment of Demodex blepharitis. TP-03 is also being developed for the treatment of Meibomian Gland Disease.

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, TP-05, future events and Tarsus' plans for and the anticipated benefits of its product candidates including TP-03, TP-05, the timing, objectives and results of the clinical studies 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 and 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 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, 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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