



Tarsus Announces Positive Topline Results from Carpo, a Phase 2a Proof-of-Concept “Tick-Kill” Trial Evaluating TP-05 (lotilaner) for the Prevention of Lyme Disease

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TP-05 demonstrated tolerability and statistically significant tick mortality, suggesting potential for on-demand Lyme disease prophylaxis

IRVINE, Calif., Feb. 22, 2024 (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 Phase 2a Carpo trial evaluating TP-05 (lotilaner), a novel, investigational oral therapeutic for the prevention of Lyme disease.

In this randomized, double-blind, placebo-controlled trial, the ability of TP-05 to kill ticks attached to subjects with a single treatment of TP-05 (low or high dose) was evaluated compared to placebo. Sterile, non-pathogenic nymphal ticks were placed on the skin of healthy human volunteers at two separate instances (one day prior to dosing and on Day 30 after dosing). Tick mortality was evaluated within 24 hours of attachment after each placement. In most cases, ticks must be attached for 36-48 hours or more before Lyme disease can be transmitted, so killing ticks within 24 hours of attachment can greatly increase the probability of disease prevention ¹.

Both the high and low doses of TP-05 demonstrated a statistically significant benefit in killing ticks compared to placebo. Specifically, after the Day 1 tick challenge, mean tick mortality was 97.0% ($\pm$ 1.4 standard error, SE) and 92.0% ($\pm$ 6.3 SE) for the high and low doses of TP-05, respectively, compared to only 5.0% ($\pm$ 2.5 SE) for placebo ($p < 0.0001$).

Similarly, at the 30-day challenge, mean tick mortality at 24 hours after placement was 89.0% ($\pm$ 11.1 SE) and 91.0% ($\pm$ 6.1 SE) for the high and low doses of TP-05, respectively, compared to only 9.0% ($\pm$ 8.0 SE) for placebo ($p < 0.001$). No statistically significant differences in tick mortality were observed between the two TP-05 treatment arms, and TP-05 was generally well tolerated.

“Lyme disease remains a growing public health concern associated with long-term consequences for millions of patients and an estimated \$1 billion dollar price tag for the U.S. healthcare system,” said Bobby Azamian, M.D., Ph.D., Chief Executive Officer and Chairman of Tarsus. “We are highly encouraged by these early proof-of-concept data and the opportunity to bring forward a novel, on-demand, oral treatment that addresses the root cause of disease – the ticks that transmit the bacteria that cause Lyme disease.”

“The risk of infection from tick-borne diseases, such as Lyme disease and other serious infections, is growing at an alarming rate, and the consequences can be debilitating and long-lasting,” said Linden Hu, M.D., the Paul and Elaine Chervinsky Professor in Immunology at Tufts University School of Medicine and Principal Investigator for the Carpo trial. “The tick-kill rates seen at Day 1 and Day 30 suggest that TP-05 may have the potential to provide both rapid and durable protection against multiple tick-borne diseases, which would be a welcome alternative to vaccines in the prevention armamentarium.”

About TP-05

TP-05 is an oral systemic formulation of lotilaner, a well-characterized anti-parasitic agent that selectively inhibits parasite-specific GABA-Cl 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.

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 considered to be 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, as well as cardiac complications. 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. XDEMZY® (lotilaner ophthalmic solution) 0.25% is FDA approved in the United States for the treatment of *Demodex* blepharitis. Tarsus is also developing TP-03 as an investigational therapy for the treatment of Meibomian Gland Disease, TP-04 for the treatment of rosacea and TP-05 as an oral tablet for the prevention of Lyme disease, all 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 the potential market size for TP-05 with respect to Lyme disease prevention, anticipated benefits of its product candidates including TP-05 and its potential applicability to Lyme disease prevention, as well as that of a variety of tick-borne diseases, the timing, objectives, and results of the clinical trials including the complete clinical results of the Carpo trial, anticipated regulatory and development milestones, our ability to continue investing in our business, and the quotations of Tarsus’ management and consultants. 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, 2022 filed on March 17, 2023, the Form 10-Q for the quarter ended September 30, 2023 filed on November 9, 2023 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.

Reference:

¹ [Centers for Disease Control and Prevention. Lyme Disease Transmission.](#)

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