Tarsus Releases Data from Io and Europa Trials for TP-03 to Treat Demodex Blepharitis and Begins Enrollment and Treatment in Phase 2b/3 Saturn-1 Trial

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Phase 2 trials Io and Europa meet endpoints for novel ophthalmic therapeutic targeting Demodex mites; Saturn-1 pivotal trial enrollment now underway

IRVINE, Calif., Oct. 6, 2020 /PRNewswire/ -- Tarsus Pharmaceuticals, Inc., a late clinical-stage biopharmaceutical company, announced data from its Phase 2 trials, Io (a Phase 2a, single-arm open-label trial) and Europa (a Phase 2b, randomized vehicle-controlled trial), evaluating the safety and efficacy of TP-03, a novel ophthalmic therapeutic being developed for the treatment of Demodex blepharitis. Both studies produced data on the safety, efficacy, and tolerability of TP-03, consistent with findings from the company's previous Mars and Jupiter Phase 2 trials.

In the Phase 2a Io trial, treatment with TP-03 was effective at achieving the primary and secondary endpoints, respectively, of collarette cure in 72% of participants and mite eradication in 78% of participants at Day 42. In the Phase 2b Europa trial, statistically significant results were achieved for the primary endpoint of collarette cure by 80% of participants on TP-03 compared to 16% on vehicle ($p<0.001$) at Day 42, and the secondary endpoint of mite eradication by 73% of participants on TP-03 compared to 21% on vehicle ($p=0.003$) at Day 42. TP-03 was well tolerated and there were no reports of serious adverse events or treatment discontinuations due to adverse events in either study. Participants in Europa rated the administration of the eye drops as "neither comfortable nor uncomfortable," "comfortable," or "very comfortable" 87% of the time.

The Io and Europa trials included adults aged 18 years or older with more than 10 collarettes present on the upper lid and mild-to-severe lid margin erythema. Participants had at least 1.5 mites per lash on the upper and lower eyelids combined. One drop of the TP-03 treatment was dosed twice per day in each eye for 42 days. Enrolled participants received no treatment for blepharitis symptoms (i.e., lid hygiene) during the study, as well as 14 days prior.

Additionally, Tarsus Pharmaceuticals has commenced patient enrollment and treatment in its Saturn-1 Phase 2b/3 pivotal trial. Saturn-1 is a larger, multi-center trial with the same endpoints as the Europa Phase 2b trial. Enrollment in the Saturn-1 trial began in September 2020 and a second pivotal trial, Saturn-2, is expected to begin in 2021.

"We are happy with these Phase 2 results and are excited to proceed with our pivotal trials," said Bobak Azamian, MD, CEO at Tarsus Pharmaceuticals. "We look forward to providing further updates on TP-03's development as we reach additional clinical and commercial milestones."

Blepharitis is a common, chronic ophthalmic condition characterized by inflammation of the eyelid margin, redness, and ocular irritation. According to literature, approximately 45% of blepharitis cases in the United States may be attributed to Demodex mites. TP-03 is designed to paralyze and eradicate mites and other parasites through the inhibition of parasite-specific GABA-Cl channels.

About Tarsus Pharmaceuticals, Inc.

Tarsus Pharmaceuticals, Inc. is a late clinical-stage biopharmaceutical company focused on the development and commercialization of therapeutic candidates to address large market opportunities, initially in ophthalmic conditions, where there are limited treatment alternatives. It is advancing its pipeline to address several diseases across therapeutic categories including eye care, dermatology, and other diseases with high, unmet needs. Its lead product candidate, TP-03, is a novel therapeutic in Phase 2b/3 trials that is being developed for the treatment of Demodex blepharitis. For more information, visit www.tarsusrx.com

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