LianBio Partner Tarsus Pharmaceuticals Announces Positive Topline Data from Second Pivotal Trial of TP-03 for the Treatment of Demodex Blepharitis

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LianBio Holds Development and Commercialization Rights to TP-03 in Greater China

SHANGHAI, China and PRINCETON, N.J., May 03, 2022 (GLOBE NEWSWIRE) -- LianBio's (Nasdaq: LIAN) partner, Tarsus Pharmaceuticals, Inc. (Tarsus) yesterday announced that TP-03 (lotilaner ophthalmic solution, 0.25%) met the primary endpoint and all secondary endpoints in the Saturn-2 pivotal Phase 3 trial with a favorable safety profile, reinforcing its potential to resolve Demodex blepharitis, a highly prevalent eyelid disease. With these results, Tarsus plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2022.

"We congratulate our partner Tarsus on continuing to demonstrate clinically meaningful and statistically significant disease resolution in the second pivotal trial of TP-03," said Yizhe Wang, Ph.D., chief executive officer of LianBio. "These data reinforce TP-03's potential to become the standard of care for the treatment of Demodex blepharitis. We estimate there are approximately 43 million patients with Demodex blepharitis in China, and there are currently no therapies approved in China for these patients. We look forward to initiating our planned Phase 3 study of TP-03 in China."

LianBio licensed rights from Tarsus in March 2021 for the development and commercialization of TP-03 in Greater China. LianBio expects to initiate a registrational Phase 3 clinical trial of TP-03 in the second half of 2022 to support regulatory approval in China.

About TP-03
TP-03 (lotilaner ophthalmic solution, 0.25%) is a novel, investigational therapeutic designed to resolve the signs of Demodex blepharitis by targeting and eradicating the root cause of the disease – Demodex mite infestation. Lotilaner is a well-characterized anti-parasitic agent that paralyzes and eradicates Demodex mites by selectively inhibiting the GABA-Cl channels. It is a highly lipophilic molecule, which may promote its uptake in the oily sebum of the hair follicle where the mites reside. Tarsus has evaluated TP-03 in two pivotal trials, including Saturn-2, collectively involving 833 patients. Both trials met the primary and all secondary endpoints, with statistical significance and no serious treatment-related adverse events. If approved, TP-03 may offer treatment for millions of patients with Demodex blepharitis.

About Demodex Blepharitis
Blepharitis is a common ocular condition that is characterized by inflammation of the eyelid margin, redness and ocular irritation. Demodex blepharitis is caused by infestation of Demodex mites, the most common ectoparasite found on humans. Demodex mites cause approximately 45% of blepharitis. Currently, there are no treatments approved by the FDA or China National Medical Products Administration for Demodex blepharitis.

About LianBio
LianBio is a cross-border biotechnology company on a mission to bring transformative medicines to historically underserved patients in China and other Asian markets. Through partnerships with highly innovative biopharmaceutical companies around the world, LianBio is advancing a diversified portfolio of clinically validated product candidates with the potential to drive new standards of care across cardiovascular, oncology, ophthalmology, inflammatory disease and respiratory indications. LianBio is establishing an international infrastructure to position the company as a partner of choice with a platform to provide access to China and other Asian markets. For more information, please visit www.lianbio.com.

Cautionary Note Regarding 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. The words "plan," "continue," "estimate," "potential," "expect," "may," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements in this press release include, but are not limited to, statements concerning the potential of TP-03 to resolve Demodex blepharitis, Tarsus's plans to submit an NDA to the FDA in the second half of 2022, the Company's plans and expectations with respect to its ability to develop and bring TP-03 to patients in China, the Company's plans and expectations with respect to the initiation of its planned Phase 3 clinical trial of TP-03 in China, the potential for TP-03 to serve as a standard of care for the treatment of Demodex blepharitis, and the estimated disease prevalence of Demodex blepharitis. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully initiate and conduct its planned clinical trials and complete such clinical trials and obtain results on its expected timelines, or at all; the Company's plans to leverage data generated in its partners' global registrational trials and clinical development programs to obtain regulatory approval and maximize patient reach for its product candidates; the Company's ability to identify new product candidates and successfully acquire such product candidates from third parties; competition from other biotechnology and pharmaceutical companies; general market conditions; the impact of changing laws and regulations and those risks and uncertainties described in LianBio's filings with the U.S. Securities and Exchange Commission (SEC), including LianBio's Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent filings with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and LianBio specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. Readers should not rely upon this information as current or accurate after its publication date.

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