LianBio Doses First Patient in Registrational Phase 3 LIBRA Trial of TP-03 in Chinese Patients with Demodex Blepharitis

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- *LIBRA trial designed to support registration in China*
- *Topline results expected in the fourth quarter of 2023*

SHANGHAI and PRINCETON, N.J., Nov. 01, 2022 (GLOBE NEWSWIRE) -- LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other major Asian markets, today announced the first patient has been dosed in the Phase 3 LIBRA clinical trial of TP-03 in Chinese patients with *Demodex* blepharitis.

"Although *Demodex* blepharitis is a highly prevalent eye disease, with an estimated 43 million patients in China alone, there are currently no available therapeutics approved by either the FDA or China National Medical Products Administration," said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. "In U.S. clinical trials, TP-03 demonstrated statistically significant disease resolution and was safe and well tolerated. LianBio is committed to improving the standard of care for patients with *Demodex* blepharitis by rapidly bringing this first-in-class, innovative medicine to China. We are very pleased to be working with leading ophthalmology centers to conduct the LIBRA trial to support registration in our licensed territories."

TP-03 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, the active ingredient in TP-03, is a well-characterized agent that eradicates *Demodex* mites by selectively inhibiting the GABA-Cl channels. In two pivotal Phase 3 studies of TP-03 conducted in the United States, TP-03 met all primary and secondary endpoints, effectively resolving *Demodex* blepharitis and was safe and well tolerated. LianBio in-licensed rights from Tarsus Pharmaceuticals, Inc., for the development and commercialization of TP-03 in Mainland China, Hong Kong, Macau and Taiwan.

LIBRA is a Phase 3 multicenter, double-blind, randomized, placebo-controlled registrational study designed to evaluate the safety and efficacy of TP-03 in Chinese patients with *Demodex* blepharitis. LIBRA is expected to enroll 162 patients. The co-primary endpoints are complete collarette cure (0-2 collarettes per eyelid) and mite eradication (mite density of 0 mites per lash) at day 43. Secondary endpoints include composite cure of collarette and erythema (0-2 collarettes per eyelid and grade 0 erythema) at day 43. More information about the LIBRA trial can be found on http://www.chinadrugtrials.org.cn/index.html (CTR20220726).

LianBio expects to report topline results from the LIBRA trial in the fourth quarter of 2023.

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 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 agent that 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 eye lash follicles where the mites reside. TP-03 was evaluated in two pivotal trials in the United States collectively involving more than 800 patients. Both trials met the primary endpoint and all secondary endpoints, with statistical significance and no serious treatment-related adverse events. Both trials also demonstrated that TP-03 was well-tolerated. The most common adverse event occurring at a frequency of >2% in TP-03 treated patients was instillation site pain/burning/stinging. All adverse events were either mild or moderate. If approved, TP-03 may offer treatment for millions of patients with *Demodex* blepharitis. TP-03 is now also being studied for the treatment of Meibomian Gland Disease in patients with *Demodex* mites.

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 "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, 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 to work with leading ophthalmology centers over the coming months to conduct the LIBRA trial, the potential for the LIBRA trial to support registration of TP-03 in the Company's licensed territories, the Company's plans and expectations with respect to the timing of reporting topline results from the LIBRA clinical trial of TP-03 in China, and the potential for TP-03 to serve as a standard of care for the treatment 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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