LianBio Completes Enrollment in Pivotal Phase 3 EXPLORER-CN Trial of Mavacamten in Chinese Obstructive Hypertrophic Cardiomyopathy Patients

August 10, 2022

• Topline data expected mid-2023

• EXPLORER-CN trial, together with PK study conducted in healthy Chinese volunteers, expected to support registration of mavacamten in China

SHANGHAI, China and PRINCETON, N.J., Aug. 10, 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 completion of enrollment in the Phase 3 EXPLORER-CN clinical study of mavacamten in Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM).

“Despite the challenges posed by the COVID-19 lockdowns in Shanghai and other cities in China, EXPLORER-CN rapidly enrolled patients,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “We believe this reflects Chinese oHCM patients’ high demand for new therapies, physician and patient enthusiasm for the compelling data generated in global clinical trials of mavacamten, and LianBio’s strong clinical development execution capabilities on the ground in China. We thank the EXPLORER-CN participants and their families for their involvement in this important clinical study as we work to make mavacamten available to the world’s largest population of oHCM patients.”

EXPLORER-CN is a Phase 3 multicenter, double-blind, randomized, placebo-controlled registrational study designed to evaluate the safety and efficacy of mavacamten in Chinese patients with symptomatic oHCM. The primary endpoint is the change in Valsalva left ventricular outflow tract (LVOT) gradient from baseline to week 30. Eligible patients will continue in a long-term extension treatment period. More information about the EXPLORER-CN trial can be found on ClinicalTrials.gov (NCT05174416) or http://www.chinadrugtrials.org.cn/index.html (CTR20212890).

“We expect to report topline results in mid-2023 and, if positive, will use the data from EXPLORER-CN and our pharmacokinetics study in combination with the data generated in the global Phase 3 EXPLORER-HCM clinical trial to support a New Drug Application submission in China,” continued Dr. Wang. “This is a critically important step in the evolution of LianBio as we prepare to advance this potentially transformative therapy towards regulatory approval in China.”

LianBio licensed rights from MyoKardia, now a wholly owned subsidiary of Bristol Myers Squibb, in August 2020 for the development and commercialization of mavacamten in Mainland China, Hong Kong, Macau, Taiwan, Thailand and Singapore. Mavacamten was granted Breakthrough Therapy Designation in China for the treatment of patients with oHCM in February 2022. In April 2022, mavacamten was approved by the U.S. Food and Drug Administration under the brand name Camzyos for the treatment of symptomatic New York Heart Association (NYHA) class II-III oHCM to improve functional capacity and symptoms. LianBio expects to report topline data in from the Phase 3 EXPLORER-CN clinical study of mavacamten in mid-2023.

About Hypertrophic Cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is a chronic, progressive disease in which excessive contraction of the heart muscle and reduced ability of the left ventricle to fill can lead to the development of debilitating symptoms and cardiac dysfunction. HCM is estimated to affect one in every 500 people globally. The most frequent cause of HCM is mutations in the heart muscle proteins of the sarcomere. In both obstructive and non-obstructive HCM patients, exertion can result in fatigue or shortness of breath, interfering with a patient’s ability to participate in activities of daily living. HCM has also been associated with increased risks of atrial fibrillation, stroke, heart failure and sudden cardiac death.

About Camzyos (mavacamten)

Camzyos™ (mavacamten) is the first and only cardiac myosin inhibitor approved by the U.S. FDA indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive HCM to improve functional capacity and symptoms. Camzyos is an allosteric and reversible inhibitor selective for cardiac myosin. Camzyos modulates the number of myosin heads that can enter “on actin” (power generating) states, thus reducing the probability of force producing (systolic) and residual (diastolic) cross-bridge formation. Excess myosin actin cross bridge formation and dysregulation of the super relaxed state are mechanistic hallmarks of HCM. Camzyos shifts the overall myosin population towards an energy sparing, recruitable, super relaxed state. In HCM patients, myosin inhibition with Camzyos reduces dynamic left ventricular outflow tract (LVOT) obstruction and improves cardiac filling pressures.

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 “expect,” “continue,” “estimate,” “potential,” “will” 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 regarding the Company’s plans and expectations to report topline results in mid-2023, to use the data from EXPLORER-CN and its PK study to support registration of mavacamten in China; the Company’s beliefs regarding Chinese oHCM patients’ demand for new therapies, physician and patient enthusiasm for mavacamten, and the Company’s strong clinical development capabilities in China; and the Company’s work with respect to its ability to develop and bring mavacamten to patients in Asia. 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.

For investor inquiries, please contact:
Elizabeth Anderson, VP Communications and Investor Relations
E: elizabeth.anderson@lianbio.com
T: +1 646 655 8390

For media inquiries, please contact:
Katherine Smith, Evoke Canale
E: katherine.smith@evokegroup.com
T: +1 619 849 5378