LianBio Completes Phase 1 Pharmacokinetic Study of Mavacamten in Healthy Chinese Volunteers

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Mavacamten demonstrated a favorable safety, tolerability and pharmacokinetic profile in healthy Chinese volunteers

Study was conducted in parallel with ongoing Phase 3 EXPLORER-CN trial of mavacamten in obstructive hypertrophic cardiomyopathy to support regulatory approval in China

SHANGHAI, China and PRINCETON, N.J., May 09, 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 a Phase 1 pharmacokinetic study of mavacamten in healthy Chinese volunteers.

A single oral administration of mavacamten showed no new safety signals in Chinese healthy adult subjects. The data demonstrated a favorable pharmacokinetic and safety and tolerability profile comparable to that observed in the Phase 1 pharmacokinetic study of mavacamten conducted by our partner, MyoKardia, now a wholly owned subsidiary of Bristol Myers Squibb, in healthy volunteers in the United States.

The pharmacokinetic study was an open-label, parallel-group, single-center Phase 1 clinical study evaluating a single oral administration of mavacamten in 44 healthy Chinese volunteers. The study was conducted in parallel to an ongoing Phase 3 clinical trial of mavacamten in Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM). LianBio expects that the results of the pharmacokinetic trial, together with the results of its Phase 3 clinical trial, if positive, will enable it to submit a New Drug Application to the National Medical Products Administration to support regulatory approval in China.

“LianBio thanks the volunteers and clinicians for their participation in the Phase 1 pharmacokinetic study of mavacamten,” said Yizhe Wang, Ph.D., chief executive officer of LianBio. “The rapid conduct of this study supports our goal of accelerating patient access to mavacamten. With the continued progress of our ongoing EXPLORER-CN Phase 3 trial, we believe the supportive Phase 1 study brings us closer to being able to provide this potentially transformative treatment to patients living with oHCM 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. LianBio is currently conducting EXPLORER-CN, 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. 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.

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,” “believe,” “continue,” “estimate,” “potential” 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 Company’s plans and expectations with respect to its ability

to develop and bring Camzyos 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.

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