LianBio Announces First Patient Dosed in Registrational Phase 3 EXPLORER-CN Trial of Mavacamten in Chinese Patients with Obstructive Hypertrophic Cardiomyopathy

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EXPLORER-CN trial designed to support regulatory filing in Mainland China

SHANGHAI, China and PRINCETON, N.J., Jan. 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 first patient has been dosed in the Phase 3 EXPLORER-CN clinical trial of mavacamten in Chinese patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM).

“With more than one million estimated patients, China is home to the world’s largest hypertrophic cardiomyopathy population,” said Yizhe Wang, Ph.D., chief executive officer of LianBio. “In global clinical trials, mavacamten demonstrated statistically significant and clinically meaningful benefit in oHCM patients. LianBio is committed to accelerating access to this potentially transformative, first-in-class cardiac myosin inhibitor, and we have designed the pivotal EXPLORER-CN trial to support New Drug Application (NDA) filing in China.”

Mavacamten is a potential first-in-class, oral, allosteric modulator of cardiac myosin in development for the treatment of conditions in which excessive cardiac contractility and impaired diastolic filling of the heart are the underlying cause of disease. In the global Phase 3 EXPLORER-HCM trial of mavacamten in oHCM patients with New York Heart Association (NYHA) class II–III symptoms, mavacamten met all primary and secondary endpoints with statistical significance and demonstrated clinically meaningful improvement in functional status, symptoms, and quality of life. LianBio in-licensed rights from MyoKardia, now a wholly owned subsidiary of Bristol-Myers Squibb, for the development and commercialization of mavacamten in Mainland China, Hong Kong, Macau, Taiwan, Thailand and Singapore.

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. EXPLORER-CN will enroll approximately 81 patients. 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).

LianBio is also conducting a concurrent pharmacokinetic (PK) study of mavacamten in healthy Chinese volunteers. The PK study completed subject dosing in November 2021.

About Hypertrophic Cardiomyopathy
Hypertrophic cardiomyopathy, or 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 either obstructive or 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.

There are currently approximately 1.1 million[1] to 2.8 million[2] people living with HCM in China, with no existing effective drug treatment options beyond limited symptomatic relief.

About Mavacamten
Mavacamten is a potential first-in-class, oral, allosteric modulator of cardiac myosin, under investigation for the treatment of conditions in which excessive cardiac contractility and impaired diastolic filling of the heart are the underlying cause. Mavacamten reduces cardiac muscle contractility by inhibiting excessive myosin-actin cross-bridge formation that results in hypercontractility, left ventricular hypertrophy and reduced compliance. In clinical and preclinical studies, mavacamten has consistently reduced biomarkers of cardiac wall stress, lessened excessive cardiac contractility and increased diastolic compliance.

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 “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” 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 bring mavacamten to patients in Asia and the

potential for mavacamten to serve as a first-in-class cardiovascular medication. 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

1. Zou Y, et al. Prevalence of idiopathic hypertrophic cardiomyopathy in China: a population-based echocardiographic analysis of 8080 adults. Am J Med. 2004 Jan 1;116(1):14-8.

2. Maron BJ. Clinical Course and Management of Hypertrophic Cardiomyopathy. N Engl J Med. 2018 Aug 16;379(7):655-668.

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