LianBio Announces Marketing Approval of CAMZYOS® (mavacamten) in the Macau Special Administrative Region (SAR) of China

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SHANGHAI, China and PRINCETON, N.J., May 11, 2023 (GLOBE NEWSWIRE) -- LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other major Asian markets, today announced that CAMZYOS® (mavacamten) has received marketing approval for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) from the Pharmaceutical Administration Bureau of the Macau SAR.

“Hypertrophic cardiomyopathy is a cardiovascular disease that significantly impacts the quality of life of patients,” said Dr. Xiuhua Feng, Consultant of Cardiology at Kiang Wu Hospital. “We are very pleased to see the approval of mavacamten in Macau, as it will bring hope to local patients living with this chronic and debilitating condition.”

"Macau marks mavacamten’s first approval in LianBio’s licensed territories,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “This approval is a major milestone for patients in the region and demonstrates LianBio’s commitment to accelerating patient access throughout Asia to innovative new treatments.”

In April 2023, the China National Medical Products Administration (NMPA) accepted with Priority Review the New Drug Application for mavacamten for the treatment of adults with symptomatic oHCM.

In April 2023, LianBio announced positive topline results from the Phase 3 EXPLORER-CN trial investigating mavacamten for the treatment of Chinese patients with symptomatic oHCM. EXPLORER-CN met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in Valsalva left ventricular outflow tract (LVOT) gradient from baseline to week 30 compared to placebo ($p<0.001$). Additionally, mavacamten demonstrated clinically important improvements for all secondary endpoints, including change from baseline to week 30 in resting LVOT peak gradient, proportion of participants achieving a Valsalva LVOT peak gradient <30 mmHg at week 30, proportion of participants achieving a Valsalva LVOT peak gradient <50 mmHg at week 30, proportion of participants with at least one NYHA class improvement from baseline to week 30, change from baseline to week 30 in Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical Summary Score (CSS), and change from baseline to week 30 in left ventricular mass index evaluated by cardiac magnetic resonance imaging. Safety results in the trial were consistent with previous studies of mavacamten in symptomatic oHCM, and no new safety signals were reported.

About 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 oHCM to improve functional capacity and symptoms. It has also received regulatory approvals in Australia, Canada, Brazil, Switzerland and Macau. 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.

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.

About EXPLORER-CN
The EXPLORER-CN Phase 3 trial enrolled a total of 81 patients in China with symptomatic (NYHA Class II or III) oHCM. All participants had one measurable LVOT gradient (resting or provoked) ≥50 mmHg during screening. Patients were randomized 2:1 to mavacamten or placebo.

The primary endpoint for EXPLORER-CN is the change from baseline to week 30 in Valsalva LVOT gradient. Secondary endpoints include changes from baseline to week 30 in resting LVOT gradient, proportion of participants achieving a Valsalva LVOT peak gradient <30 mmHg at week 30, proportion of participants achieving a Valsalva LVOT peak gradient <50 mmHg at week 30, proportion of participants with at least one NYHA class improvement from baseline to week 30, change from baseline to week 30 in Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical Summary Score (CSS), change from baseline to week 30 in N-terminal pro B-type Natriuretic Peptide (NT-proBNP), change from baseline to week 30 in cardiac troponin, and change from baseline to week 30 in left ventricular mass index evaluated by cardiac magnetic resonance imaging.

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.

In China, there are an estimated 1.1 million to 2.8 million patients with HCM.

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, and inflammatory disease. 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,” “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 LianBio’s beliefs regarding LianBio’s ability to accelerate patient access to innovative medicines. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: LianBio’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; LianBio’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; LianBio’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, 2022 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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