LianBio Announces Marketing Approval of CAMZYOS® (mavacamten) in Singapore

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SHANGHAI, China and PRINCETON, N.J., June 26, 2023 (GLOBE NEWSWIRE) -- LianBio (Nasdaq: LIAN), a biotechnology company dedicated to bringing innovative medicines to patients in China and other Asian markets, today announced that CAMZYOS® (mavacamten) has received marketing approval for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) from the Singapore Health Sciences Authority.

“Clinical trials have demonstrated that CAMZYOS has the potential to improve symptoms, quality of life, and functional status in symptomatic oHCM,” said Dr. Lin Weiqin, Clinical Director, Heart Failure and Cardiomyopathy Programme, National University Heart Centre, Singapore (NUHCS), and Assistant Professor, Yong Loo Lin School of Medicine, National University of Singapore (NUS). “The approval of CAMZYOS in Singapore brings a much needed, effective new treatment option to our local oHCM patients.”

Marketing approval in Singapore was based on data from the Phase 3 EXPLORER-HCM trial. Results from the Phase 3 EXPLORER-HCM trial, which evaluated CAMZYOS in patients with symptomatic obstructive HCM versus placebo, met all primary and secondary endpoints with statistical significance. In EXPLORER-HCM, CAMZYOS demonstrated a clear treatment effect, with clinically meaningful improvements in exercise capacity and symptoms, and functional status, as well as clinically meaningful improvement in left ventricular outflow tract obstruction.

"LianBio is committed to bringing mavacamten to symptomatic oHCM patients in Asia,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “Mavacamten is now approved in both Singapore and Macau, with additional New Drug Applications on file in Mainland China and Hong Kong. We look forward to continuing to work with regulators in the region to accelerate access to this promising new therapeutic option for patients in need.”

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, Macau, South Korea and Singapore. 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-HCM
The EXPLORER-HCM Phase 3 trial (NCT03470545) was a double-blind, randomized, placebo-controlled, parallel group trial that enrolled a total of 251 adult patients with symptomatic (NYHA class II or III), obstructive hypertrophic cardiomyopathy. All participants had measurable left ventricular ejection fraction (LVEF) ≥55% and at least one peak LVOT gradient ≥50 mmHg (at rest or with provocation at diagnosis); in addition, Valsalva LVOT gradient ≥30 mmHg at baseline was required at screening. Ninety-two percent of patients were on background therapies of a beta blocker or calcium channel blocker. The primary endpoint was a composite functional endpoint, assessed at 30 weeks, and was defined as the proportion of patients who achieved either improvement of mixed venous oxygen tension (pVO2) by ≥1.5 mL/kg/min plus improvement in NYHA class by at least 1 or improvement of pVO2 by ≥3.0 mL/kg/min plus no worsening in NYHA class. Key secondary endpoints include impact on exercise gradient LVOT, pVO2, NYHA Class and Kansas City Cardiomyopathy Questionnaire (KCCQ) and Hypertrophic Cardiomyopathy Symptom Questionnaire (HCMSQ) at Week 30.

About 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 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 therapeutic potential of CAMZYOS and LianBio’s ability to accelerate patient access to mavacamten in Asia. 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.

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:
Josh Xu, Director of Communications
E: josh.xu@lianbio.com
T: +86 136 6140 8315

Katherine Smith, Evoke Canale
E: katherine.smith@evokegroup.com
T: +1 619 849 5378