LianBio Announces First Patient Treated in Phase 1 Trial of SHP2 Inhibitor BBP-398 in Combination with Osimertinib in Patients with Non-Small Cell Lung Cancer with EGFR Mutations

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SHANGHAI, China and PRINCETON, N.J., Aug. 03, 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 the first patient has been dosed in its Phase 1 clinical trial of BBP-398, an investigational SHP2 inhibitor, in combination with AstraZeneca's osimertinib, an epidermal growth factor receptor (EGFR) inhibitor, for the treatment of patients with non-small cell lung cancer (NSCLC) with EGFR mutations.

SHP2 is a protein-tyrosine phosphatase that links growth factor, cytokine and integrin signaling with the downstream RAS/MAPK pathway to regulate cellular proliferation and survival. Overactivity of SHP2 is a critical contributor to many forms of cancer, is a mechanism of resistance to several targeted therapies, and can suppress antitumor immunity.

EGFR mutations occur in approximately 40-50% of NSCLC cases in Asia, more than twice the rate observed in the United States. By combining SHP2 inhibition and EGFR inhibition, there is potential to prevent oncogenesis and overactive cellular proliferation.

"BBP-398 is a potential best-in-class SHP2 inhibitor that was designed to maximize combination potential," said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. "EGFR-mutant non-small cell lung cancer patients who develop resistance to osimertinib currently have limited treatment options, and we look forward to evaluating BBP-398's ability to restore sensitivity to osimertinib when used as a combination agent."

The multi-center, open-label Phase 1 trial is designed to evaluate the safety, tolerability, pharmacokinetics, and anti-tumor activity of BBP-398 in combination with osimertinib in patients with locally advanced or metastatic NSCLC with EGFR mutations. The trial includes a dose escalation phase, followed by expansion cohorts. In July 2023, LianBio announced a clinical supply agreement with AstraZeneca in China to procure osimertinib for this trial.

About BBP-398
BBP-398 is a SHP2 inhibitor that is being developed for difficult-to-treat cancers and was founded through a collaboration between BridgeBio and The University of Texas MD Anderson Cancer Center's Therapeutics Discovery division. SHP2 is a protein-tyrosine phosphatase that links growth factor, cytokine and integrin signaling with the downstream RAS/ERK MAPK pathway to regulate cellular proliferation and survival. LianBio and BridgeBio have a strategic collaboration for clinical development and commercialization of BBP-398 in combination with various agents in solid tumors such as non-small cell lung cancer, colorectal and pancreatic cancer, in mainland China and other Asian markets. In May 2022, BridgeBio entered an exclusive license with Bristol Myers Squibb to develop and commercialize BBP-398 in all indications worldwide, except for Mainland China, Macau, Hong Kong, and Taiwan, Thailand, Singapore, and South Korea. BBP-398 is also being studied by BridgeBio and its clinical collaborators, including Bristol Myers Squibb for combination with OPDIVO® (nivolumab) in patients with advanced solid tumors with KRAS mutations; and with Amgen for combination with LUMAKRAS® (sotorasib), Amgen's KRAS G12C inhibitor, in patients with advanced solid tumors with KRAS G12C mutations.

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 "believe," "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 the differentiation of BBP-398 and BBP-398's potential to restore sensitivity to EGFR inhibitors when used in a combination setting. 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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