LianBio Doses First Patient in Phase 1 Trial of BBP-398 in Chinese Patients with Advanced Solid Tumors

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SHANGHAI, China and PRINCETON, N.J., Nov. 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 first patient has been dosed in its Phase 1 clinical trial of BBP-398, a SHP2 inhibitor, in Chinese patients with advanced solid tumors.

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.

In this two-part, open label, dose escalation and dose expansion Phase 1 study, safety and preliminary anti-tumor activity will be examined. Part 1 is a dose escalation to establish the recommended Phase 2 dose (RP2D) of BBP-398 and assess the pharmacokinetic profile of BBP-398 in Chinese patients. Part 2 is a dose expansion to examine preliminary antitumor activity in patients with advanced or metastatic EGFR-mutant non-small cell lung cancer (NSCLC).

“SHP2 inhibition has the potential to overcome resistance mechanisms to various important standard of care cancer therapies,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “Data generated to date suggest BBP-398 has a promising pharmacokinetic profile that could provide key advantages as a backbone combination therapy. Chinese NSCLC patients have approximately 2-3-fold higher EGFR mutation rate than Western patients, and while EGFR inhibitors represent an important advancement in treatment, many patients go on to develop treatment-resistant disease. We look forward to conducting this monotherapy study and progressing BBP-398 into combination trials with an EGFR inhibitor beginning in 2023.”

LianBio has a strategic collaboration with BridgeBio Pharma, Inc. for the development and commercialization of BBP-398 in Mainland China, Hong Kong, Macau, Taiwan, South Korea, Singapore and Thailand. LianBio plans to develop BBP-398 in combination with various oncology medications in solid tumors, including for the treatment of NSCLC.

LianBio expects to initiate a Phase 1 clinical trial of BBP-398 in combination with an EGFR inhibitor in Chinese patients with EGFR-mutant NSCLC in the first half of 2023.

About BBP-398
BBP-398 is a SHP2 inhibitor that is being developed for difficult-to-treat cancers. 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. 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.

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 “estimate,” “potential,” “expect,” “may,” “could,” “promising,” “progress,” “plan,” “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 concerning the potential of BBP-398 as a SHP2 inhibitor, the Company’s plans and expectations with respect to its ability to develop and bring BBP-398 to patients in China, the Company’s plans and expectations with respect to the timing and criteria of its Phase 1 and any combination trials, and the potential for BBP-398 to serve as a backbone combination therapy. 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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