# LianBio Announces Topline Results from Phase 2a Proof of Concept Trial Evaluating Infigratinib in Patients with Gastric Cancer & Receipt of Breakthrough Therapy Designation in China

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SHANGHAI, China and PRINCETON, N.J., June 06, 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 positive topline results from a Phase 2a proof of concept trial evaluating infigratinib in Chinese patients with locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 (FGFR2) gene amplification.

The Phase 2a trial is a multicenter, open-label, single-arm study in China designed to evaluate the safety and efficacy of infigratinib 125 mg QD in patients with locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with FGFR2 gene amplification and other advanced solid tumors with FGFR alterations who have received at least two prior lines of systemic therapy. The primary endpoint is objective response rate (ORR). Secondary endpoints include duration of response, safety, disease control rate, progression-free survival, and overall survival (NCT05019794).

The topline results from the gastric cancer and gastroesophageal junction adenocarcinoma cohort demonstrated a confirmed ORR of 25.0% (n=20). The observed median duration of response (DOR) was 3.8 months. 57.1% of patients had received two prior lines of systemic therapy, 33.3% of patients had received three prior lines of systemic therapy, and 9.5% of patients had received more than three prior lines of systemic therapy. The most common treatment-emergent adverse events of any grade (greater than or equal to 20 percent) included hyperphosphatemia, anemia, alanine aminotransferase increase, aspartate aminotransferase increase, white blood cell count decrease, neutrophil count decrease, diarrhea, constipation, palmar-plantar erythrodysesthesia, lipase increase, blood alkaline phosphatase increase, and blood bilirubin increase.

“Gastric cancer impacts a disproportionately high number of patients in China,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “Patients whose disease has progressed on existing treatment options face a poor prognosis today. The topline data from this proof-of-concept trial suggest infigratinib has the potential to provide meaningful clinical benefit in third-line or later gastric cancer. We look forward to further investigating the efficacy and safety of infigratinib in this patient population in a Phase 2 study designed to support registration in China that we plan to initiate next year.”

Based on these data, the China National Medical Products Administration (NMPA) granted Breakthrough Therapy Designation to infigratinib for the treatment of gastric cancer. Breakthrough Therapy Designation in China is designed to expedite the development and review of investigational therapeutics for the treatment of serious and life-threatening diseases that have demonstrated preliminary evidence indicating advantages of the therapy over currently available treatment options. Drugs with Breakthrough Therapy Designation can access additional communication channels and technical guidance from the Center for Drug Evaluation of the NMPA in addition to potential accelerated approval pathways.

LianBio expects to work with investigators to present detailed results from the clinical trial at an upcoming medical meeting.

**About infigratinib**
Infigratinib is an orally administered, ATP-competitive, tyrosine kinase inhibitor of fibroblast growth factor receptor (FGFR) that targets the FGFR protein, blocking downstream activity. In clinical studies, infigratinib demonstrated a clinically meaningful rate of tumor shrinkage (overall response rate) and duration of response in cholangiocarcinoma. It is currently being evaluated in clinical studies for locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma, and other advanced solid tumors with FGFR genomic alterations.

LianBio licensed rights from QED Therapeutics, a subsidiary of BridgeBio Pharma, for the development and commercialization of infigratinib for human prophylactic and therapeutic uses in all cancer indications in Mainland China, Hong Kong, and Macau. Infigratinib was granted Breakthrough Therapy Designation in China for the treatment of patients with gastric cancer in 2023.

**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 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 “expect,” “plan,” “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 potential for infigratinib to provide meaningful clinical benefit in third-line or later gastric cancer; LianBio’s expected timeline and plans to further investigate the safety and efficacy of infigratinib in a Phase 2 study in gastric cancer patients; LianBio’s expectations that its Phase 2 study of infigratinib will support registration in China; and LianBio’s expectation that it will work with investigators to present detailed results at an upcoming medical meeting. 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.

In addition, topline and interim data from clinical trials may not be indicative of final results, and the results of early clinical trials may not be indicative of the results of later clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and/or clinical safety studies will be required by the NMPA or similar regulatory authorities in other jurisdictions, or that subsequent studies will not match results seen in prior studies. As a result, topline data should be viewed with caution until the final data are available.

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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