LianBio Announces Presentation of Data from Phase 2a Study of Infigratinib in Patients with Gastric Cancer at ESMO Congress 2023

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SHANGHAI, China and PRINCETON, N.J., Oct. 25, 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 presentation of efficacy and safety data from a Phase 2a study evaluating infigratinib in Chinese patients with locally advanced or metastatic gastric cancer (GC) or gastroesophageal junction adenocarcinoma (GEJ) with fibroblast growth factor receptor-2 (FGFR2) gene amplification. The data were presented by Dr. Jiajia Yuan, Peking University Cancer Hospital and Institute, at the 2023 European Society for Medical Oncology (ESMO) Congress in a poster titled, “Efficacy and Safety of Infigratinib in Patients with Locally Advanced or Metastatic Gastric Cancer or Gastroesophageal Junction Adenocarcinoma and FGFR2 Gene Amplification.” (Poster No. 1527P)

The study enrolled 21 GC and GEJ patients with FGFR2 gene amplification. 20 patients (95.2%) who had ≥1 post-baseline tumor assessment per RECIST v1.1 were evaluable. Confirmed objective response rate (cORR) was 23.8% (95% CI: 8.2 – 47.2), disease control rate (DCR) was 76.2% (95% CI: 52.8 – 91.8) and median duration of response (DOR) was 3.8 months (95% CI: 3.6 – NE). Median progression-free survival (mPFS) was 3.3 months (95% CI: 2.3 – 4.5) and median overall survival (mOS) was 8.0 months (95% CI: 4.1 – NE). Among 20 evaluable patients who had post-baseline assessments, cORR was 25.0% (95% CI: 8.7–49.1) and DCR was 80.0% (95% CI: 56.3–94.3).

Infigratinib was generally well tolerated with a manageable safety profile. There were no treatment-related adverse events (TRAEs) leading to dose discontinuation, death, or drug-induced liver injury.

“The encouraging data presented at ESMO highlight infigratinib’s potential to provide a meaningful clinical benefit to patients whose disease has progressed on other treatments,” said Yizhe Wang, Ph.D., Chief Executive Officer of LianBio. “China has an acute need for new effective treatment options as there is a disproportionately higher number of patients with gastric cancer in the region.”

FGFR pathway aberrations are common in multiple cancer types, including gastric cancer. Infigratinib is an ATP-competitive, FGFR1-3 selective oral tyrosine kinase inhibitor. Infigratinib received Breakthrough Therapy Designation from the China National Medical Products Administration (NMPA) for the treatment of gastric cancer.

About the Study
The Phase 2 clinical 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 (Cohort 1) and other advanced solid tumors with FGFR alterations (Cohort 2) 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).

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. 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 “may”, “continue,” “potential,” 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 infigratinib’s potential to provide a meaningful clinical benefit to patients whose disease has progressed on other treatments. 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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