# BridgeBio Pharma and LianBio Announce First Patient Treated in Phase 2a Trial of Infigratinib in Patients with Gastric Cancer and Other Advanced Solid Tumors

August 25, 2021

**Palo Alto, CA and Shanghai and Princeton, NJ** - August 25, 2021 – LianBio, a biotechnology company dedicated to bringing paradigm-shifting medicines to patients in China and other major Asian markets, and BridgeBio Pharma, Inc. (Nasdaq: BBIO) today announced the first patient has been treated in a Phase 2a clinical trial of infigratinib in patients with locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 (FGFR2) gene amplification and other advanced solid tumors with FGFR genomic alterations.

"Infigratinib is a potent and selective FGFR inhibitor that has demonstrated compelling clinical activity across multiple tumor types with FGFR alterations," said Yizhe Wang, Ph.D., chief executive officer of LianBio. "Given the disproportionately high prevalence rate of gastric cancer in China, LianBio is pursuing a region-specific development strategy focused on this area of great unmet need. This study marks LianBio's first trial initiation and demonstrates our continued progress in delivering potentially transformational medicines to patients in Asia."

TRUSELTIQ™ (infigratinib) is an oral selective inhibitor of FGFR1-3 that is approved in the United States for the treatment of patients with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or other rearrangement as detected by an FDA-approved test. It is also being further evaluated in clinical trials based on demonstration of clinical activity in patients with advanced urothelial carcinoma with FGFR3 genomic alterations. LianBio in-licensed rights from BridgeBio for infigratinib for development and commercialization in Mainland China, Hong Kong and Macau.

The Phase 2a trial is a multicenter, open-label, single-arm study in China designed to evaluate the safety and efficacy of infigratinib 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. The primary endpoint is objective response rate (ORR). Secondary endpoints include duration of response, safety, disease control rate, progression-free survival and overall survival.

Preclinical data have demonstrated the potential infigratinib may have for patients with gastric cancer. These results, published in Cancer Discovery, demonstrated tumor regression in multiple in vivo FGFR2 amplified gastric models.1

"We believe that infigratinib could have a meaningful impact for people living with gastric cancer as well as many other cancers with FGFR alterations, and are pleased LianBio is initiating this clinical trial in China where more therapeutic options are needed to match the growing diagnosis rate," said BridgeBio founder and chief executive officer Neil Kumar, Ph.D. "On the heels of TRUSELTIQ recently obtaining accelerated approval in the United States, we are hopeful that this trial will yield pivotal results in another subset of cancer patients as we continue to build our portfolio of oncology indications with the aim of reaching as many people in need as possible."

**About TRUSELTIQ™ (infigratinib)**

TRUSELTIQ (infigratinib) is an orally administered, ATP-competitive, tyrosine kinase inhibitor of fibroblast growth factor receptor (FGFR) that received accelerated approval from the FDA in the United States for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. TRUSELTIQ targets the FGFR protein, blocking downstream activity. In clinical studies, TRUSELTIQ demonstrated a clinically meaningful rate of tumor shrinkage (overall response rate) and duration of response. TRUSELTIQ is not FDA-approved for any other indication in the United States and is not approved for use by any other health authority, including any Chinese or other Asian health authority. It is currently being evaluated in clinical studies for first-line cholangiocarcinoma, urothelial carcinoma (bladder cancer), locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma, and other advanced solid tumors with FGFR genomic alterations.

**About BridgeBio Pharma, Inc.**

BridgeBio is a biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases and cancers with clear genetic drivers. BridgeBio's pipeline of over 30 development programs

ranges from early science to advanced clinical trials and its commercial organization is focused on delivering the company's first two approved therapies. BridgeBio was founded in 2015 and its team of experienced drug discoverers, developers and innovators are committed to applying advances in genetic medicine to help patients as quickly as possible. For more information visit bridgebio.com.

**About LianBio**
LianBio's mission is to catalyze the development and accelerate availability of paradigm-shifting medicines to patients in China and other major Asian markets, through partnerships that provide access to innovative therapeutic discoveries with a strong scientific basis and compelling clinical data. LianBio collaborates with world-class partners across a diverse array of therapeutic and geographic areas to build out a broad and clinically validated pipeline with the potential to impact patients with unmet medical needs. For more information, please visit www.lianbio.com

**About the LianBio and BridgeBio Pharma, Inc. Strategic Alliance**
In August 2020, LianBio entered into a strategic alliance with BridgeBio, a commercial-stage biopharmaceutical company focused on genetic diseases and cancers with clear genetic drivers, to develop and commercialize BridgeBio's programs in China and other major Asian markets. This strategic relationship initially focuses on two of BridgeBio's targeted oncology drug candidates: FGFR inhibitor infigratinib, for the treatment of FGFR-driven tumors, and SHP2 inhibitor BBP-398, in development for tumors driven by MAPK pathway mutations. The agreement also provides LianBio with preferential future access in China and certain other major Asian markets to more than 20 drug development candidates currently owned or controlled by BridgeBio. This collaboration is designed to advance and accelerate BridgeBio's programs in China and other major Asian markets, allowing BridgeBio and LianBio to potentially bring innovation to large numbers of patients with high unmet need.

**BridgeBio Pharma, Inc. Forward-Looking Statements**
This press release contains forward-looking statements. Statements we make in this press release may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act, and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including statements relating to: the timing and success of the Phase 2a clinical trial of infigratinib in patients with locally advanced or metastatic gastric cancer or gastroesophageal junction adenocarcinoma with fibroblast growth factor receptor-2 (FGFR2) gene amplification, and other advanced solid tumors with FGFR genomic alterations; the planned approval of infigratinib by foreign regulatory authorities in China and the necessary clinical trial results, and timing and completion of regulatory submissions related thereto; and the competitive environment and clinical and therapeutic potential of infigratinib; reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation: the safety, tolerability and efficacy profile of infigratinib observed to date may change adversely in ex-U.S. clinical trials, ongoing analyses of trial data or subsequent to commercialization; foreign regulatory agencies may not agree with our regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted; the continuing success of the BridgeBio and LianBio strategic alliance; and potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and clinical trials, supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy; as well as those set forth in the Risk Factors section of BridgeBio Pharma, Inc.'s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent SEC filings, which are available on the SEC's website at www.sec.gov. Except as required by law, each of BridgeBio and QED disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. Moreover, BridgeBio and QED operate in a very competitive environment in which new risks emerge from time to time. These forward-looking statements are based on each of BridgeBio's and QED's current expectations, and speak only as of the date hereof.

*1 Guagnano, V., Kauffman, A., Wörle, S., et al. "FGFR Genetic Alterations Predict for Sensitivity to NVP-BGJ398, a Selective Pan-FGFR Inhibitor." Cancer Discovery 2 (2012): 1118-1133.*

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