



NEWS RELEASE

bridgebio announces clinical collaboration with amgen to study bbp-398, a potentially best-in-class shp2 inhibitor, in combination with lumakras® (sotorasib) in advanced solid tumors with the kras g12c mutation

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- First clinical combination study of BBP-398 and LUMAKRAS set to evaluate safety and preliminary efficacy in solid tumors with the KRAS G12C mutation

PALO ALTO, Calif., Jan. 13, 2022 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) (BridgeBio), a commercial-stage biopharmaceutical company focused on genetic diseases and cancers, today announced a non-exclusive clinical collaboration with Amgen Inc. (Amgen) to evaluate the combination of BBP-398, a potentially best-in-class SHP2 inhibitor, with LUMAKRAS® (sotorasib), a KRAS^{G12C} inhibitor, in patients with advanced solid tumors with the KRAS G12C mutation.

The Phase 1/2 study will include a dose escalation period followed by dose expansion and optimization, and is designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of BBP-398 in combination with LUMAKRAS. Under the terms of the non-exclusive collaboration, BridgeBio will sponsor the study and Amgen will provide a global supply of LUMAKRAS.

BBP-398 is a potent small-molecular inhibitor of SHP2 developed in collaboration with 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. By combining SHP2 inhibition with KRAS^{G12C} inhibition in patients with the KRAS G12C mutation, there is potential that the investigational combination could prevent oncogenesis and overactive cellular proliferation.

“Overactivity of the MAPK pathway is a significant cause of many types of difficult-to-treat cancers and by combining these two agents, we aim to reduce the oncogenic potential of tumor cells,” said Frank McCormick, Ph.D., chairman of oncology at BridgeBio. “Building on our collaborations with Bristol Myers Squibb and LianBio, we are excited to be working with Amgen on this new collaboration. By harnessing the power of BBP-398 as a potentially best-in-class SHP2 inhibitor with LUMAKRAS, we are hopeful that we will be able to provide substantial relief for cancer patients in need. We will continue to pursue additional collaborations that we believe hold promise for patients.”

KRAS mutations occur in approximately 17% of malignant solid tumors. BBP-398, as a monotherapy or in combination with other targeted therapies, could potentially be a promising therapy for patients with the KRAS G12C mutation.

BridgeBio is currently advancing its Phase 1 clinical trial of its SHP2 inhibitor, BBP-398, in patients with solid tumors driven by mutations in the MAPK signaling pathway, including RAS and receptor tyrosine kinase genes. BBP-398 is part of BridgeBio’s growing precision oncology pipeline and is one of 14 programs in the broader portfolio that are being advanced in the clinic or commercial setting.

About BBP-398

BBP-398 is a potentially best-in-class SHP2 inhibitor. Earlier this year, BridgeBio entered a non-exclusive, co-funded clinical collaboration with Bristol Myers Squibb to evaluate the combination of BBP-398 with OPDIVO® (nivolumab) in patients with advanced solid tumors with KRAS mutations. BridgeBio previously also entered into a strategic collaboration with LianBio for clinical development and commercialization of BBP-398 in combination with various agents in solid tumors such as non-small cell lung cancer, colorectal cancer and pancreatic cancer in mainland China and other major Asian markets.

About BridgeBio Pharma, Inc.

BridgeBio Pharma (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 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](https://www.bridgebio.com) and follow us on [LinkedIn](#) and [Twitter](#).

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 expectations, plans, and prospects regarding the success of our non-exclusive clinical collaboration with Amgen, the timing and success of a Phase 1/2 study to evaluate the safety and preliminary efficacy of BBP-398 in combination with LUMAKRAS in patients with advanced solid tumors with the KRAS G12C mutation, the ability of combining SHP2 inhibition with KRAS^{G12C} inhibition in patients with the KRAS G12C mutation to prevent oncogenesis and overactive cellular proliferation, our ability to provide substantial relief for cancer patients in need, the promise of targeted therapies for patients with KRAS mutations, the success and status of current and future relationships with third-party collaborators and academic partners, the continuing success of our clinical collaboration with Bristol Myers Squibb to evaluate the combination of BBP-398 with OPDIVO[®] (nivolumab), and the potential ability of our product candidates to treat genetically driven diseases and cancers with clear genetic drivers, reflect our current views about our plans, intentions, expectations, strategies and prospects, and are based on the information currently available to us and on assumptions we have made and are not forecasts, promises nor guarantees. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by these 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 number of risks, uncertainties and assumptions, including, but not limited to, the success of our product candidates to treat genetically driven diseases and cancers with clear genetic drivers, the continuing success of our collaboration with Amgen and other third parties, our ability to enter into future collaboration agreements, 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 risks set forth in the Risk Factors section of BridgeBio’s most recent Annual Report on Form 10-K and BridgeBio’s other SEC filings. Moreover, we operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. Except as required by applicable law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

BridgeBio Media Contact:

Grace Rauh

Grace.rauh@bridgebio.com

(917) 232-5478

BridgeBio Investor Contact:

Katherine Yau

katherine.yau@bridgebio.com

(516) 554-5989