



NEWS RELEASE

bridgebio pharma announces first lung cancer patient dosed in phase 1/2 trial and us fda fast track designation for shp2 inhibitor bbp-398 in combination with amgen's lumakras® (sotorasib)

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- BBP-398, an investigational SHP2 inhibitor, is a potentially optimal agent for use in combination therapies given its continuous, once-daily dosing in addition to synergistic activity with other agents to treat cancers driven by KRAS G12C mutations
- The combination of investigational therapy BBP-398 and LUMAKRAS, if successful, has the potential to address the serious unmet need for patients with KRAS G12C-mutated non-small cell lung cancer (NSCLC).
- This combination trial is designed to target NSCLC driven by a KRAS G12C mutation, one of the most common oncogenic mutations in the United States (US) and European Union (EU); 13% of NSCLC tumors have a KRAS G12C mutation with approximately 30,000 people diagnosed in the US each year
- Preclinical findings demonstrated synergistic efficacy for the combination of the two therapies in a KRAS G12C-mutated NSCLC cell line-derived xenograft model

PALO ALTO, Calif., Oct. 11, 2022 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc., (Nasdaq: BBIO) (BridgeBio), a commercial-stage biopharmaceutical company focused on genetic diseases and cancers, today announced that the first patient with non-small cell lung cancer (NSCLC) has been dosed in its Phase 1/2 clinical trial of BBP-398, an investigational SHP2 inhibitor, with Amgen Inc.'s (Amgen) LUMAKRAS® (sotorasib), the first and only currently

approved targeted treatment for patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, in advanced solid tumors with the KRAS G12C mutation.

Approximately 30,000 people are diagnosed with KRAS G12C-mutated NSCLC in the US each year and the KRAS G12C mutation is one of the most frequent oncogenic mutations in the US and Europe. By combining SHP2 inhibition with KRAS G12C inhibition in patients with the KRAS G12C mutation, there is potential to prevent oncogenesis and overactive cellular proliferation.

"The survival rate following a diagnosis of NSCLC with a KRAS mutation is extremely poor. We are hopeful that by launching this clinical trial with Amgen, we may be able to fill the current gap in unmet medical need for these cancer patients," said Frank McCormick, Ph.D., chairman of oncology at BridgeBio. "We are grateful the FDA has granted our program Fast Track designation and are hopeful it will allow us to address the needs of these patients more quickly following diagnosis."

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. The dose escalation period will enroll patients with all solid tumors with a KRAS G12C mutation and participants will be eligible regardless of previous exposure to a KRAS G12C inhibitor. The dose expansion period will enroll patients with NSCLC with a KRAS G12C mutation who have not previously been exposed to a KRAS G12C inhibitor. Initial data is expected by the end of 2024.

Additionally, the US Food and Drug Administration (FDA) granted Fast Track designation for the investigation of BBP-398 in combination with LUMAKRAS for adult patients with previously treated, KRAS G12C-mutated, metastatic NSCLC. The FDA's Fast Track designation is designed to drive the development and expedite the review process for medicines under investigation for serious conditions with unmet medical needs.

"To date, preclinical data for SHP2 inhibition has shown promise in unlocking possible combination strategies to treat patients suffering from a range of cancers, including NSCLC. By combining SHP2 inhibition with KRAS G12C inhibition, there is potential for this therapeutic arsenal to be impactful for patients since it could prevent overactive cellular proliferation and oncogenesis. I am extremely pleased to see that work from our group and others has now reached the clinic, where we will be able to study the benefit it could have for cancer patients with KRAS G12C mutations," said Benjamin G. Neel, M.D., Ph.D., Co-founder of Navire Pharma Inc. (Navire), a BridgeBio company, and Director of the L/I Perlmutter Cancer Center at NYU Langone and Professor of Medicine at NYU Grossman SoM.¹

"People with metastatic NSCLC with a KRAS mutation often do not respond well to standard chemotherapy and immunotherapy options. They might have a worse prognosis than patients without a KRAS mutation and it is

essential to deliver better therapeutic options to people with this difficult-to-treat cancer. I am hopeful that by partnering with BridgeBio on this study we may be able to provide substantial relief for patients with a serious unmet need,” said Rohit Joshi, M.D., Director for Cancer Research SA (CRSA) and Associate Professor at the University of Adelaide.

In May 2022, BridgeBio entered into an exclusive license agreement with Bristol Myers Squibb to develop and commercialize BBP-398 in oncology worldwide, except for in mainland China and other Asian markets. These territories are part of BridgeBio’s separate strategic collaboration with LianBio announced in 2020. The 2022 agreement with Bristol Myers Squibb expands upon the earlier agreement between the companies signed in 2021 to investigate the combination of BBP-398 with OPDIVO® (nivolumab) in patients with advanced solid tumors with KRAS mutations.

BridgeBio has a non-exclusive clinical collaboration with Amgen to evaluate the combination of BBP-398 with LUMAKRAS in patients with advanced solid tumors with the KRAS G12C mutation.

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. Initial Phase 1 data from the ongoing BBP-398 trial is expected in 2023.

OPDIVO® (nivolumab) is a trademark of Bristol-Myers Squibb Company.

About BBP-398

BBP-398 is a SHP2 inhibitor that is being developed for difficult-to-treat cancers and was founded through a 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. In May 2022, BridgeBio entered an exclusive license with Bristol Myers Squibb to develop and commercialize BBP-398, a potentially best-in-class SHP2 inhibitor. Additionally, BridgeBio has 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 and pancreatic cancer, in mainland China and other Asian markets and clinical collaborations; with Bristol Myers Squibb for combination with OPDIVO® (nivolumab) in patients with advanced solid tumors with KRAS mutations; and with Amgen for combination with LUMAKRAS® (sotorasib), Amgen’s KRAS G12C inhibitor, in patients with advanced solid tumors with KRAS G12C mutations.

About BridgeBio Pharma, Inc.

BridgeBio Pharma (BridgeBio) is a commercial-stage 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 development programs ranges from early science to advanced clinical trials. 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 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 our 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, including the potential availability of initial data at the end of 2024, the FDA's grant of Fast Track designation for the investigation of BBP-398 in combination with LUMAKRAS for adult patients with previously treated, KRAS G12C-mutated, metastatic NSCL, the ability of combining SHP2 inhibition with KRAS G12C inhibition in patients with the KRAS G12C mutation to prevent oncogenesis and overactive cellular proliferation, the availability of initial Phase 1 data from the ongoing BBP-398 trial expected in 2023, 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.

¹Dr. Benjamin Neel is a co-founder of Navire and currently holds equity in the company. Though not directly involved in this trial, the clinical trial was developed in part based on prior work performed in his lab. Questions regarding Dr. Neel's interests as they may relate to this trial can be directed to NYU Langone Health.

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