



NEWS RELEASE

bridgebio pharma and affiliate navire pharma announce dosing of first patient in phase 1 clinical trial of shp2 inhibitor bbp-398 for tumors driven by ras and receptor tyrosine kinase mutations

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SAN FRANCISCO, Nov. 13, 2020 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) and affiliate Navire Pharma, Inc. announced today that the first patient has been dosed in a 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 was developed through a collaboration with The University of Texas MD Anderson Cancer Center's **Therapeutics Discovery division**.

In this two-part Phase 1 study, safety and preliminary anti-tumor activity will be examined. Part 1 is a dose escalation to establish the recommended Phase 2 dose (RP2D) of BBP-398. Part 2 will examine preliminary anti-tumor activity in four cohorts of patients with certain molecular alterations. Those cohorts include advanced KRAS G12C mutant non-small cell lung carcinoma (NSCLC), advanced KRAS G12C mutant non-NSCLC, advanced solid tumors with other MAPK pathway mutations and advanced EGFR-mutant NSCLC. David S. Hong, professor of Investigational Cancer Therapeutics at MD Anderson, will serve as the lead principal investigator for the study.

The primary objective of the study is to evaluate the safety of BBP-398 in advanced cancer patients, with secondary objectives assessing preliminary anti-tumor activity, including objective response rates and duration of response. Patients enrolling in the study must have a diagnosis of advanced (primary or recurrent) or metastatic solid tumor with potentially susceptible genomic alterations in the MAPK pathway (excluding BRAF V600X).

“SHP2 inhibitors have the potential to be effective additions to the therapeutic arsenal for difficult-to-treat cancers by overcoming multiple mechanisms that tumors use to evade treatments,” said Eli Wallace, Ph.D., chief scientific officer of oncology at BridgeBio, Navire’s parent company. “This study is a critical step in understanding the potential that BBP-398 has for patients with tumors driven by RAS or other MAPK-pathway activating mutations and informing our future clinical development activities.”

SHP2, a conserved protein tyrosine phosphatase, plays a critical role in cell signaling and growth, which are important in the progression of cancer. As SHP2 regulates receptor tyrosine kinase signaling pathways commonly overly activated in cancer, targeting SHP2 may offer a potential new approach to treat this disease.

BBP-398 was initially discovered and developed by a team of scientists in MD Anderson’s **Institute for Applied Cancer Science (IACS)** and **Translational Research to Advance Therapeutics and Innovation in Oncology (TRACTION)** platforms, both engines within the Therapeutics Discovery division. The ongoing research is supported by Navire through a global licensing and development agreement with MD Anderson.

About BridgeBio Pharma

BridgeBio is a team of experienced drug discoverers, developers and innovators working to create life-altering medicines that target well-characterized genetic diseases at their source. BridgeBio was founded in 2015 to identify and advance transformative medicines to treat patients who suffer from Mendelian diseases, which are diseases that arise from defects in a single gene, and cancers with clear genetic drivers. BridgeBio’s pipeline of over 20 development programs includes product candidates ranging from early discovery to late-stage development. For more information visit bridgebio.com.

About Navire Pharma

Navire Pharma, an affiliate of **BridgeBio**, in collaboration with MD Anderson’s Therapeutics Discovery division, is developing inhibitors of SHP2 as targeted therapeutics for the treatment of multiple cancers. Together with patients and physicians, the company aims to bring safe, effective treatments to market as quickly as possible. For more information, please visit navirepharma.com

BridgeBio Pharma 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, and Section 21E of the Securities Exchange Act of 1934, as amended, 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 Securities Exchange Act and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including statements relating to Navire Pharma's clinical development plans, clinical trial results, timing and completion of clinical trials, Phase 1 study design and objectives, competitive environment, and clinical and therapeutic potential of BBP-398, an SHP2 inhibitor, 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, Navire Pharma's ability to continue its planned clinical development for BBP-398 and the timing and success of any such continued clinical development, the therapeutic potential of BBP-398, an SHP2 inhibitor, in patients with solid tumors driven by mutations in the MAPK signaling pathway, including RAS and receptor tyrosine kinase genes, and the continuing success of Navire Pharma's collaboration with The University of Texas MD Anderson Cancer Center's Institute for Applied Cancer Sciences, as well as those set forth in the Risk Factors section of BridgeBio Pharma, Inc.'s most recent Quarterly Report on Form 10-Q and our other SEC filings. Except as required by law, we and Navire Pharma assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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