NEWS RELEASE

bridgebio announces fda clearance of ind application for bbo-8520, a first-in-class direct inhibitor of krasg12c (on)

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- The United States Food and Drug Administration (FDA) has cleared the investigational new drug (IND) application for BBO-8520, a first-in-class orally bioavailable and potentially highly potent small molecule direct inhibitor of $KRAS^{G12C}$ that binds to the Switch II pocket in both the GTP-bound (ON) and GDP-bound (OFF) state conformations of $KRAS^{G12C}$

- BBO-8520 is expected to significantly improve outcomes for patients with $KRAS^{G12C}$ driven malignancies by providing optimal target coverage and addressing mechanisms of adaptive resistance to first generation $KRAS^{G12C}$ (OFF) state inhibitors

- BridgeBio expects to initiate enrollment of patients with $KRAS^{G12C}$ mutant non-small cell lung cancer in the ONKORAS-101 trial in the first half of 2024

PALO ALTO, Calif., Jan. 03, 2024 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) (“BridgeBio” or the “Company”), a commercial-stage biopharmaceutical company focused on genetic diseases and cancers, has announced that the United States Food and Drug Administration (FDA) has cleared the investigational new drug (IND) application for BBO-8520, a first-in-class orally bioavailable and highly potent small molecule direct inhibitor of $KRAS^{G12C}$ (ON) state. BBO-8520 binds covalently to the Switch II pocket in both the GTP-bound (ON) and GDP-bound (OFF) state conformations of $KRAS^{G12C}$, leading to rapid and robust inhibition of $KRAS^{G12C}$ activity.

BBO-8520’s ability to inhibit the (ON) state should provide optimal target coverage and address $KRAS^{G12C}$

amplification and receptor tyrosine kinase activation - the two key mechanisms of adaptive resistance to current (OFF) state inhibitors. BBO-8520 drives substantial tumor growth inhibition in multiple preclinical models, even after emergence of resistance to sotorasib, an FDA approved (OFF) state inhibitor of $KRAS^{G12C}$.

“Clinical results from the first generation of $KRAS^{G12C}$ inhibitors suggest that compounds with better potency and the ability to target the ON state are likely to lead to better outcomes,” said Frank McCormick, Ph.D., Chairman of Oncology at BridgeBio, David A. Wood Distinguished Professor of Tumor Biology and Cancer Research at UCSF and advisor to the National Cancer Institute’s RAS Initiative at Frederick National Laboratory for Cancer Research (FNL). “BBO-8520 is the most potent G12C inhibitor with an IND, and the only compound that directly binds and targets the ON state. We hope that this drug will bring significantly improved benefit for patients suffering from $KRAS^{G12C}$ cancers.”

BBO-8520’s discovery was the result of a collaboration between the RAS Initiative FNL, Lawrence Livermore National Laboratory and BridgeBio. It is specifically designed to provide patients afflicted with $KRAS^{G12C}$ mutant cancers with a best-in-class, oral small molecule therapy that directly targets the tumor at its source - oncogenic $KRAS^{G12C}$ GTP-bound (ON) signaling. Enrollment of patients with $KRAS^{G12C}$ mutant non-small cell lung cancer into the ONKORAS-101 trial is expected to begin in H1 of this year.

About BridgeBio Pharma, Inc.

BridgeBio Pharma, Inc. 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 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,” “hopes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “continue,” “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. These forward-looking statements, including statements relating to the clinical and therapeutic

potential of BBO-8520, including the expectation that BBO-8520 will significantly improve outcomes for patients with $KRAS^{G12C}$ driven malignancies by providing optimal target coverage and addressing mechanisms of adaptive resistance to first generation $KRAS^{G12C}$ (OFF) state inhibitors, our clinical development program for BBO-8520, including the expected timeline to initiate enrollment of patients with $KRAS^{G12C}$ mutant non-small cell lung cancer in the ONKORAS-101 trial in the first half of 2024, the statements regarding the potency and potential benefit of BBO-8520 and of our clinical trial in the quotes of Dr. McCormick, and the timing of these events, reflect our current views about our plans, intentions, expectations and strategies, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, and strategies 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 number of risks, uncertainties and assumptions, including, but not limited to, initial and ongoing data from our clinical trials not being indicative of final data, the design and success of ongoing and planned clinical trials, difficulties with enrollment in our clinical trials, adverse events that may be encountered in our clinical trials, the FDA or other regulatory agencies not agreeing with our regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, potential adverse impacts due to the global COVID-19 pandemic such as delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, the impacts of current macroeconomic and geopolitical events, including changing conditions from the COVID-19 pandemic, hostilities in the Middle East and Ukraine, increasing rates of inflation and rising interest rates, on our overall business operations and expectations, as well as those risks set forth in the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2022 and our other filings with the U.S. Securities and Exchange Commission. Moreover, we operate in a very competitive and rapidly changing environment in which new risks emerge from time to time. These forward-looking statements are based upon the current expectations and beliefs of our management as of the date of this press release and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. 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.

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