NEWS RELEASE

bridgebio pharma announces u.s. food and drug administration (fda) acceptance of new drug application (nda) for acoramidis for the treatment of patients with transthyretin amyloid cardiomyopathy (attr-cm)

2024-02-05

- Accepted with Prescription Drug User Fee Act (PDUFA) action date of November 29, 2024; FDA not currently planning to hold an advisory committee meeting to discuss application

- Marketing Authorization Application accepted by the European Medicines Agency (EMA) with additional global regulatory submissions planned

- In ATTRibute-CM, acoramidis treatment demonstrated an 81% absolute survival rate and a 0.29 observed mean annual cardiovascular-related hospitalization (CVH) frequency, as well as improvements for a large proportion of patients on laboratory and functional measures

- ATTRibute-CM results also demonstrated rapid clinical benefit on the composite endpoint of all-cause mortality (ACM) and CVH in patients treated with acoramidis, with time-to-first event Kaplan-Meier curves separating at month 3 and continuing to diverge steadily through Month 30

PALO ALTO, Calif., Feb. 05, 2024 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) (“BridgeBio” or the “Company”), a commercial-stage biopharmaceutical company focused on genetic diseases and cancers, today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company’s New Drug

Application (NDA) for acoramidis, an investigational drug for the treatment of ATTR-CM. The application was based on positive results from ATTRibute-CM, the Company's Phase 3 study designed to evaluate the efficacy and safety of acoramidis, an investigational, next-generation, orally-administered, highly potent, small molecule stabilizer of transthyretin (TTR). The FDA has set an action date of November 29, 2024 under the PDUFA. The FDA also notified the Company that it is not currently planning to hold an advisory committee meeting to discuss the application.

"The FDA's acceptance of our NDA submission for review reinforces our belief in acoramidis and its potential to make an important contribution to the care of patients with ATTR-CM," said Jonathan Fox, MD, PhD, President and Chief Medical Officer of BridgeBio Cardiorenal. "We look forward to the upcoming review process and the potential for approval in the United States. Similarly, with the European Marketing Authorization Application accepted and with plans to extend our submissions to other countries and regions, we are committed to making acoramidis available to patients."

In July 2023, BridgeBio **announced** positive results from ATTRibute-CM, reporting a highly statistically significant result, demonstrated by a Win Ratio of 1.8 ($p<0.0001$) on the primary endpoint (a hierarchical analysis prioritizing in order: ACM, then frequency of CVH, then change from baseline in N-terminal prohormone of brain natriuretic peptide (NT-proBNP), then change from baseline in 6-minute walk distance (6MWD)). Acoramidis was well-tolerated, with no safety signals of potential clinical concern identified. BridgeBio has also presented analyses from ATTRibute-CM at the European Society of Cardiology Congress 2023 and at the American Heart Association Scientific Sessions 2023.

"As part of our mission, we seek to improve the lives of patients with amyloidosis by providing support to them and their caregivers throughout their journey. There is a need for more treatment options that can help fill the significant unmet need that exists for patients today. We are excited by BridgeBio's recent NDA acceptance from the FDA, which we hope moves us one step closer to having acoramidis available as a treatment for the ATTR-CM community," said Isabelle Lousada, president and CEO of the Amyloidosis Research Consortium, a global nonprofit organization dedicated to advancements in amyloidosis.

The Company also received acceptance of its Marketing Authorization Application with the European Medicines Agency and is preparing for additional global regulatory submissions.

About BridgeBio

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 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," "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, therapeutic and market potential of our programs and product candidates, including our clinical development program for acoramidis for patients with transthyretin amyloid cardiomyopathy, including statements relating to the FDA's planned actions regarding our NDA for acoramidis for the treatment of ATTR-CM, our preparation and plans for additional regulatory submissions, the statements regarding the potential outcome of FDA's review of the NDA, the potential of acoramidis to make an important contribution to the care of patients with ATTR-CM and the commitment and hope to make acoramidis available as a treatment for ATTR-CM to patients in the quotes of Dr. Fox and Ms. Lousada, 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.

BridgeBio Media Contact:
Vikram Bali
contact@bridgebio.com
(650)-789-8220