



NEWS RELEASE

bridgebio pharma presents additional data and analyses from its phase 3 attribute-cm study in transthyretin amyloid cardiomyopathy (attr-cm) at esc-hf, including that acoramidis treatment significantly reduced all-cause mortality in a pre-specified sensitivity analysis of the entire study population

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- In a pre-specified Cochran-Mantel-Haenszel sensitivity analysis applied to the entire intention-to-treat (ITT) population of the study (N=632), acoramidis significantly reduced all-cause mortality (p=0.04), with no safety signals of potential clinical concern
- Among ATTRibute-CM participants enrolled with Stage 4 chronic kidney disease (CKD) (N=21), acoramidis treatment was associated with proportionally fewer deaths compared with placebo, with no safety signals of potential clinical concern
- At Month 30 of the ATTRibute-CM study, acoramidis treatment resulted in a statistically significant and clinically important reduction in the progressive decline in health-related quality of life as assessed by the EuroQoL Health Outcomes Assessment tool, EQ-5D-5L
- Acoramidis treatment also reduced the decline in health status and quality of life as shown by statistically significant and clinically meaningful benefits in the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall

summary score, and supported by numerical and consistent benefits in individual KCCQ domains

- In ATTRibute-CM, acoramidis significantly improved NT-proBNP indices that can be a signal of ATTR-CM disease progression and be predictive of subsequent mortality risk

PALO ALTO, Calif., May 13, 2024 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a commercial-stage biopharmaceutical company focused on genetic diseases and cancers, announced positive results of four new analyses from its Phase 3 ATTRibute-CM study of acoramidis in ATTR-CM at the European Society of Cardiology (ESC) Heart Failure Congress 2024. ATTRibute-CM was designed to study the efficacy and safety of acoramidis, an investigational, next-generation, orally-administered, highly potent, small molecule stabilizer of TTR.

The data presented at ESC Heart Failure included a sub-analysis comparing acoramidis to placebo in Stage 4 CKD and results from a pre-specified ITT sensitivity analysis **shared by Steen Hvitfeldt Poulsen**, M.D., Ph.D., D.M.Sc. of the Aarhus University Hospital, DK. Key results included:

- In a pre-specified sensitivity analysis applied to the entire ITT population (N=632), acoramidis significantly reduced all-cause mortality (ACM) as assessed by the Cochran-Mantel-Haenszel (CMH) test (p=0.04)
- In high-risk participants with Stage 4 CKD (N=21), acoramidis treatment was associated with 25% relative risk reduction in deaths at Month 30 versus placebo, consistent with the observations in the modified intention-to-treat (mITT) population (N=611)
- No safety signals of potential clinical concern were identified

"ATTRibute-CM breaks new ground studying the efficacy and safety of acoramidis, a next-generation TTR stabilizer, as the only ATTR-CM outcomes trial to include patients with eGFR <25 mL/min/1.73m²," said Dr. Poulsen. "We recruited patients with Stage 4 CKD (eGFR between 15 and 30 mL/min/1.73m²) to explore the safety of acoramidis in this very high-risk population; in a pre-specified all-cause mortality (ACM) efficacy analysis of the total ITT population including these patients, acoramidis demonstrated a statistically significant benefit within 30 months. Even in this very high-risk Stage 4 CKD group, ACM favored active treatment with no safety signals of clinical concern."

Additional acoramidis presentations at ESC Heart Failure included:

- **Health-related quality of life in patients with transthyretin amyloid cardiomyopathy treated with acoramidis: an EQ-5D-5L analysis from the ATTRibute-CM study**, presented by Peter Van Der Meer, M.D., Ph.D., cardiologist, chair of the Department of Experimental Cardiology and professor of Heart Failure and Translational Cardiology at University Medical Centre Groningen, NL

- Acoramidis is the only ATTR-CM product candidate assessed with the EuroQoL Health Outcomes Assessment tool EQ-5D-5L and demonstrated a statistically significant and clinically important reduction in the progressive decline in health-related quality of life
- **Improved health-related quality of life in acoramidis-treated patients with ATTR-CM, demonstrated by improvements in KCCQ scores**, presented by Marianna Fontana, M.D., Ph.D., Professor of Cardiology and Honorary Consultant Cardiologist at the National Amyloidosis Centre, Division of Medicine, University College London, UK
 - Acoramidis treatment reduced the decline in health status and quality of life as shown by statistically significant and clinically meaningful benefits in the KCCQ overall summary score, and supported by numerical and consistent benefits in individual KCCQ domains
- **Acoramidis significantly improves NT-proBNP indices that indicate ATTR-CM disease progression and predict subsequent mortality: insights from the ATTRibute-CM study**, presented by Pablo Garcia-Pavia, M.D., Ph.D., Iron Gate Majadahonda University Hospital, ES
 - In separate publications, increase in NT-proBNP has been proposed as a metric signaling disease progression (Progressor Index 1) and has been shown to predict mortality in wild-type ATTR-CM at 12 months after diagnosis (Progressor Index 2). Acoramidis slows disease progression as measured by significant improvement in these Progressor Indices.

Based on the positive results from ATTRibute-CM, BridgeBio submitted a New Drug Application to the U.S. Food and Drug Administration, which has been accepted with a PDUFA action date of November 29, 2024, and a Marketing Authorization Application to the European Medicines Agency, with a decision expected in 2025. BridgeBio has granted exclusive rights to Bayer to commercialize acoramidis for ATTR-CM in Europe.

About BridgeBio Pharma, Inc.

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

BridgeBio and Bayer European License for Acoramidis – About the Collaboration

In March 2024, BridgeBio granted Bayer exclusive license to commercialize acoramidis as a treatment for patients with transthyretin amyloid cardiomyopathy (ATTR-CM) in Europe. Acoramidis is an investigational, highly potent and selective small molecule, under development as an orally administered transthyretin (TTR) stabilizer for the



treatment of patients with ATTR-CM a progressive fatal disease presenting as an infiltrative, restrictive cardiomyopathy resulting in heart failure.

This partnership leverages Bayer's long legacy of expertise in cardiovascular disease and its established European cardiovascular infrastructure paired with BridgeBio's leadership in the emerging field of ATTR-CM.

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," "continues," "estimates," "expects," "hopes," "intends," "may," "plans," "projects," "remains," "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. These forward-looking statements, including statements relating to expectations, plans, and prospects regarding the success and potential benefits to us of our exclusive license granted to Bayer to commercialize acoramidis as a treatment for patients with ATTR-CM in Europe; the clinical, therapeutic and market potential of our clinical development program for acoramidis; the potential benefits of acoramidis to ATTR-CM patients; the statements related to the planned actions and decisions of the FDA and the EMA regarding our NDA and MAA submissions for acoramidis for the treatment of ATTR-CM; and the potential outcomes and expected timing of regulatory reviews by the FDA and the EMA, 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 preclinical studies and clinical trials not being indicative of final data, the potential size of the target patient populations our product candidates are designed to treat not being as large as anticipated, the design and success of ongoing and planned clinical trials, future regulatory filings, approvals and/or sales, the FDA or such 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, the continuing success of our collaborations, including our partnership with Bayer, potential volatility in our share price, uncertainty regarding any impacts due to global health emergencies such as COVID-19, including 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 hostilities in Ukraine and in Israel and the Gaza Strip,

increasing rates of inflation and rising interest rates, on our business operations and expectations, as well as those risks set forth in the Risk Factors section of our most recent Annual Report on Form 10-K 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