



NEWS RELEASE

open-label extension data confirms sustained benefit of acoramidis on cardiovascular outcomes, including statistically significant reduction in acm within 36 months

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- Acoramidis demonstrated the earliest known time to separation in cardiovascular outcomes in the ATTRIBUTE-CM study (3 months), with statistically significant risk reduction of 36% on All-Cause Mortality (ACM) alone at Month 36 within the Open Label Extension
- The continued curve separation of the composite endpoint of ACM and recurrent cardiovascular-related hospitalizations (CVH) emphasizes the importance of early intervention resulting in early and sustained clinical benefits, with acoramidis demonstrating 46% ($p < 0.0001$) and 48% ($p < 0.0001$) reductions in the composite endpoint of ACM and recurrent CVH at Months 36 and 42, respectively
- The preliminary results from this ongoing OLE study were also **simultaneously published in Circulation**
- A New Drug Application for acoramidis for the treatment of ATTR-CM is currently under review with the FDA, with a PDUFA action date of November 29, 2024

PALO ALTO, Calif., Nov. 18, 2024 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a new type of biopharmaceutical company focused on genetic diseases, presented positive initial outcomes from the ATTRIBUTE-CM open-label extension (OLE) study of acoramidis in ATTR-CM at the American Heart Association (AHA) Scientific Sessions. ATTRIBUTE-CM was designed to evaluate the efficacy and safety of

acoramidis, an investigational, near-complete, orally-administered, small molecule stabilizer of TTR. The preliminary results from this ongoing OLE study were also **simultaneously published in Circulation**. The OLE study involves 389 participants who completed the 30-month ATTRibute-CM Phase 3 study.

“Results from the ATTRibute-CM OLE continue to showcase the potential of acoramidis, with ongoing data across the study suggesting that early intervention with this stabilizer leads to early separation from placebo, with sustained benefit for patients with ATTR-CM,” said Daniel Judge, M.D., professor of medicine and cardiology at the Medical University of South Carolina. “The prescribing community is eager to have another important treatment option given the remaining high unmet need for ATTR-CM patients.”

Key initial results from the OLE study, presented by Dr. Judge at AHA, show that continuous treatment with acoramidis led to:

- A confirmed sustained improvement relative to placebo in time to first event (CVH or ACM) starting at Month 3 in ATTRibute-CM
- A statistically significant reduction in ACM alone of 36% by Month 36 ($p=0.009$) and 34% by Month 42 ($p=0.006$), as assessed by the Stratified Cox proportional hazards model
- A significant reduction of composite ACM and CVH by 46% at Month 36 ($p<0.0001$) and 48% at Month 42 ($p<0.0001$), as assessed by negative binomial regression, building upon the previously presented 42% reduction at Month 30 in ATTRibute-CM
- Evidence of early benefit in patients who crossed over from placebo to acoramidis after Month 30 as compared to extrapolated placebo curve reinforces the early separation seen previously in ATTRibute-CM
- Acoramidis continues to be well tolerated, with no new clinically significant safety signals identified in this long-term evaluation

The OLE data build on previously reported results from ATTRibute-CM in which acoramidis demonstrated clinically important treatment effects on mortality, CVH, and quality of life, further supporting that greater transthyretin (TTR) stabilization can improve clinical outcomes for patients. This included a 50% reduction in the cumulative frequency of CVH relative to placebo at Month 30.

“We are pleased to share the initial results from the ongoing open-label extension study of ATTRibute-CM, which showcase the sustained benefits of acoramidis treatment for patients with ATTR-CM,” said Jonathan Fox, M.D., Ph.D., chief medical officer of BridgeBio Cardiorenal. “Coupled with acoramidis’ earliest time to separation of any known ATTR-CM treatment on clinical outcomes at 3 months, these analyses continue to support acoramidis as a

meaningful first line option.”

In addition to the featured science oral presentation at AHA, BridgeBio also shared three moderated posters:

- Costs and Healthcare Resource Utilization in Transthyretin Amyloid Cardiomyopathy Exceeds That of Generalized Heart Failure
- Evolving Baseline Risk in Patients with Transthyretin Amyloid Cardiomyopathy: A Systematic Literature Review of Clinical Trials
- Acoramidis Improved Survival in Patients with Transthyretin Cardiac Amyloidosis Regardless of Prior Cardiovascular Hospitalization

These findings reinforce the importance of an effective therapy that reduces CVH and improves survival in patients with ATTR-CM.

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 (BridgeBio) is a new type of biopharmaceutical company founded to discover, create, test and deliver transformative medicines to treat patients who suffer from genetic diseases. 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](#), [Twitter](#) and [Facebook](#).

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 the impact of acoramidis on clinical outcomes, including the reduction of ACM and CVH, TTR stabilization and the benefits of early intervention; potential benefits of acoramidis; the statements related to the planned actions and decisions of the U.S. Food and Drug Administration and the European Medicines Agency regarding our New Drug Application and Marketing Authorization Application submissions for acoramidis for the treatment of ATTR-CM; and the potential outcomes and expected timing of regulatory reviews by the U.S. Food and Drug Administration and the European Medicines Agency, and the corresponding statistically significant benefits on clinical event outcomes; and the clinical, therapeutic and market potential of our clinical development program and timeline for acoramidis 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 design and success of ongoing and planned clinical trials, future regulatory filings, approvals and/or sales, the U.S. Food and Drug Administration 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, potential volatility in our share price, uncertainty regarding any impacts due to global health emergencies, 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.

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