



NEWS RELEASE

bridgebio pharma presents cardiac magnetic resonance (cmr) imaging evidence consistent with clinical improvement observed in the attribute-cm phase 3 study in patients with transthyretin amyloid cardiomyopathy (attr-cm)

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- In this exploratory substudy, treatment with acoramidis was associated with possible cardiac structural and functional improvement compared with placebo, with potential cardiac amyloid regression
- The data demonstrate that targeting near-complete transthyretin (TTR) stabilization with acoramidis may enable cardiac remodeling and functional recovery in patients with ATTR-CM
- These results are the first prospective, longitudinal evaluation of cardiac structure and function by CMR imaging in a double-blind, placebo-controlled, interventional study in ATTR-CM
- The findings from this study build upon positive results from BridgeBio's global ATTRibute-CM Phase 3 trial, wherein the primary endpoint was met (Win Ratio of 1.8) with a high statistical significance ($p < 0.0001$); the substudy data are consistent with the cardiovascular clinical benefits observed with acoramidis
- Acoramidis was well-tolerated, with no safety signals of potential clinical concern observed
- BridgeBio's New Drug Application (NDA) has been accepted by the U.S. Food and Drug Administration (FDA) with a PDUFA action date of November 29, 2024; a Marketing Authorization Application (MAA) for acoramidis has been



accepted by the European Medicines Agency (EMA), with an expected decision in 2025

PALO ALTO, Calif., April 07, 2024 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a commercial-stage biopharmaceutical company focused on genetic diseases and cancers, today presented results from the exploratory CMR imaging substudy of ATTRibute-CM, its Phase 3 trial of acoramidis in ATTR-CM. These data were presented at the American College of Cardiology (ACC) Annual Scientific Sessions & Expo in a **moderated poster session** by Yousuf Razvi, M.D. of University College London. 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. Based on the positive results from ATTRibute-CM, BridgeBio submitted an NDA to the U.S. FDA, which has been accepted with a PDUFA action date of November 29, 2024, and an MAA to the European Medicines Agency, with a decision expected in 2025.

"CMR is the reference non-invasive imaging method to evaluate cardiac structure, function, and amyloid burden in patients with ATTR-CM. The results shown in the imaging substudy are indicative of potential improvement of cardiac structure and function in patients with ATTR-CM, consistent with the clinical outcomes with acoramidis treatment observed in the ATTRibute-CM Phase 3 clinical trial. The impact on cardiac amyloid load highlights the potential that acoramidis could lead to cardiac amyloid regression in a proportion of patients with ATTR-CM, which we have not observed in such a controlled clinical trial to date," said Marianna Fontana, M.D., Ph.D., Professor of Cardiology and Honorary Consultant Cardiologist at the National Amyloidosis Centre, Division of Medicine, University College London, and Principal Investigator of the Substudy.

CMR imaging was performed at baseline before the first dose in 35 participants or within three months after the first dose in 17 participants (range, 14-105 days); subsequent CMR imaging was performed at months 12, 24, and 30 in those individuals who were available to undergo imaging, which was influenced by survival. Images were read centrally at the National Amyloidosis Centre in a fashion blinded to other clinical data. Findings included:

- Key CMR imaging parameters measuring cardiac structure, including mean indexed left ventricular mass, were found to be stable or have a trend towards improvement on acoramidis vs. deteriorated on placebo over 30 months
- Treatment with acoramidis preserved or was associated with a trend towards improvement in measures of cardiac function including left ventricular ejection fraction and stroke volume compared to initial measures, and relative to placebo

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: all-cause mortality, then frequency of cardiovascular hospitalization, then change from baseline in N-terminal prohormone of brain natriuretic peptide, then change from baseline in 6-minute walk distance).

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](#). In February 2024, BridgeBio shared positive results of a single-arm Phase 3 study of acoramidis in Japanese patients with ATTR-CM, including no mortality observed in the trial at 30 months.

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 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," "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 our programs and product candidates, including our clinical development program for acoramidis for patients with transthyretin amyloid cardiomyopathy, the timing and success of our clinical development programs, the progress of our ongoing and planned clinical trials of acoramidis for patients with transthyretin amyloid cardiomyopathy, including the expectations of receiving a PDUFA action from the FDA on November 29, 2024 and receiving a decision from the EMA on the MAA for acoramidis in 2025, the expected intellectual property protection of acoramidis, our planned interactions with regulatory authorities, the statements regarding the potential clinical benefits or of potential benefits for ATTR-CM patients in the quotes of Dr. Fontana, 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, 2023 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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