



NEWS RELEASE

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

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- NDA submission is based on positive results from ATTRibute-CM Phase 3 study, including 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 (ACM), then frequency of cardiovascular-related hospitalization (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))
- In ATTRibute-CM, acoramidis treatment demonstrated an 81% absolute survival rate and a 0.29 observed mean annual 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 ACM and CVH in patients treated with acoramidis
- Acoramidis was well-tolerated, with no safety signals of potential clinical concern identified

PALO ALTO, Calif., Dec. 05, 2023 (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 it has submitted an NDA for acoramidis to the U.S. FDA 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 submission of the acoramidis NDA marks an important milestone in the journey for acoramidis, a novel, near-complete TTR stabilizer. The totality of the evidence consistently point to the potential to provide important clinical benefits over current therapeutic options for patients living with ATTR-CM," said Jonathan Fox, President and Chief Medical Officer of BridgeBio Cardiorenal. "The opportunity to register acoramidis with the FDA brings us that much closer to making it broadly available as an important treatment option for ATTR-CM in the US and, soon to follow, globally. We extend our deep appreciation to all of the patients who participated in our clinical trials, their families and caregivers, our dedicated investigators and other collaborators, and our BridgeBio team, who all helped make this possible."

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 NT-proBNP, then change from baseline in 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. The results included an 81% absolute survival rate on treatment and a 0.29 observed mean annual CVH frequency on treatment; additionally, among subjects on acoramidis that completed a Month 30 visit, 45% of subjects improved from baseline in NT-proBNP, 40% of subjects improved from baseline in 6MWD, and 13% of subjects improved from baseline in New York Heart Association (NYHA) classification. The results also included placebo and acoramidis time-to-first event Kaplan-Meier curves for a composite of ACM and CVH that separated at Month 3 and continued to diverge steadily through Month 30.

The FDA has a 60-day filing review period to determine whether the NDA is complete and accepted for review. The Company intends to submit additional marketing authorization applications to global health authorities in 2024.

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](https://www.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, 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, our planned interactions with regulatory authorities, including our intention to submit additional marketing authorization applications to global health authorities in 2024, the statements regarding the potential benefit of our clinical trial or of our product candidate in the quotes of Dr. Fox, 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 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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