NEWS RELEASE

bridgebio pharma announces publication of positive results from phase 3 attribute-cm study of acoramidis for patients with transthyretin amyloid cardiomyopathy (attr-cm) in the new england journal of medicine

2024-01-10

- ATTRibute-CM demonstrated a significant treatment effect of acoramidis on the primary endpoint (a hierarchical analysis inclusive of all-cause mortality (ACM) and frequency of cardiovascular-related hospitalization (CVH)), with a Win Ratio of 1.8 ($p<0.0001$)

- Acoramidis demonstrated an observed 30-month survival rate of 80.7% in the treatment arm of ATTRibute-CM; recent data from the U.S. Social Security Administration estimated 30-month survival at 85% in an age-matched cohort of the general population; similarly, the annualized CVH rate of 0.29 in the treatment arm can be viewed in the context of the annual overall hospitalization rate of 0.26 in the U.S. Medicare population

- Acoramidis is the only intervention to demonstrate cardiovascular outcomes benefit in a prospective clinical trial in the contemporary ATTR-CM population to the Company's knowledge

- Acoramidis was well-tolerated, with no safety signals of potential clinical concern identified

- BridgeBio has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) and intends to submit marketing authorization applications to additional regulatory bodies in 2024

PALO ALTO, Calif., Jan. 10, 2024 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a commercial-stage biopharmaceutical company focused on genetic diseases and cancers, announced that positive results from its Phase 3 ATTRibute-CM study of acoramidis for patients with ATTR-CM were published in the **New England Journal of Medicine (NEJM)**. ATTRibute-CM was designed to study the efficacy and safety of acoramidis, an investigational, next-generation, orally-administered, small molecule stabilizer of transthyretin (TTR).

"The consistent benefits of acoramidis treatment demonstrated by the ATTRibute-CM results, especially in the context of contemporary ATTR-CM care, are striking and encourage its potential use," said Professor Julian Gillmore, M.D., Ph.D., head of University College London's Centre for Amyloidosis and research lead at the UK National Amyloidosis Centre. "Given the efficacy and safety of acoramidis demonstrated in this trial, I am hopeful that it will soon be available to the benefit of the growing global population of patients diagnosed with ATTR-CM."

The ATTRibute-CM study demonstrated a significant treatment effect of acoramidis in the primary analysis that compared, in a hierarchical manner, all-cause mortality (ACM), cardiovascular-related hospitalization (CVH), N-terminal prohormone of brain natriuretic peptide (NT-proBNP), and 6-minute walk distance (6MWD). Findings presented in the NEJM support acoramidis as an effective and safe treatment option for patients with ATTR-CM and reinforce the hypothesis that greater stabilization of TTR may be associated with improved clinical outcomes. Additional findings in the publication include:

- The majority of comparisons in the primary hierarchical analysis (58% in the associated Win Ratio) were determined by the first two components of ACM and CVH; statistical significance was also achieved on a F-S test with those two cardiovascular outcomes parameters alone
- Statistically significant treatment benefit was observed for change from baseline in 6MWD, Kansas City Cardiomyopathy Questionnaire (KCCQ), and serum TTR
- The observed 30-month survival rate of 74.3% in the placebo arm of ATTRibute-CM is greater than the observed 30-month survival rate of 70.5% in the combined tafamidis treatment arms of ATTR-ACT, the only previously reported cardiovascular outcomes study in ATTR-CM
    - As a contemporary benchmark for placing the survival rate of 80.7% in the treatment arm of ATTRibute-CM into context, recent data from the U.S. Social Security Administration estimated 30-month survival at 85% in an age-matched cohort of the general population
    - Similarly, the annualized CVH rate in the treatment arm of ATTRibute-CM of 0.29 can be viewed in the context of data on the annual overall hospitalization rate of 0.26 in the U.S. Medicare population.
- Serum TTR was promptly and consistently elevated throughout the study in patients receiving acoramidis as a result of near-complete stabilization of the protein
- Acoramidis was well-tolerated, with no safety signals of potential clinical concern identified

“These results add to the totality of the available data supporting the concept that the greater the degree of stabilization of tetrameric TTR, the greater the observed clinical benefit,” said Jonathan Fox, M.D., Ph.D., president and chief medical officer of BridgeBio Cardiorenal. “With the submission of our NDA to register acoramidis with the FDA, and with additional regional and national regulatory submissions planned, we look forward to making acoramidis available to patients who might benefit from its demonstrated efficacy and safety.”

In July, BridgeBio **announced** positive topline results from ATTRibute-CM. BridgeBio has also presented additional detailed results from ATTRibute-CM at the European Society of Cardiology Congress 2023 in **August** and at the American Heart Association Scientific Sessions 2023 in **November**.

The Company submitted a New Drug Application to the U.S. FDA in 2023 and intends to submit additional marketing authorization applications to regulatory bodies 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** 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, including our planned interactions with regulatory authorities, our intention to submit additional marketing authorization applications in 2024, the statements regarding the potential benefit of our clinical trial or of our product candidate or the potential availability of our product candidate to patients who might benefit from it in the

quotes of Dr. Gillmore and 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.

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