



NEWS RELEASE

First Participant Dosed with Acoramidis in ACT-EARLY, the First Ever ATTR Primary Prevention Study

2025-05-13

- ATTRibute-CM, BridgeBio's Phase 3 clinical trial of acoramidis in patients with ATTR-CM, achieved statistical significance in reducing the risk of ACM or first CVH versus placebo in ATTRv-CM patients (59.1% risk reduction), establishing the mechanistic hypothesis that stabilizing TTR may delay or prevent ATTRv-CM
- ACT-EARLY is a registrational, randomized, double blind, placebo controlled, event driven prevention study that will enroll ~600 asymptomatic carriers of a pathogenic TTR variant. Diagnosis of ATTRv disease will be evaluated as the primary analysis of the study
- In the ACT-EARLY study, BridgeBio will partner globally with ATTR amyloidosis treating physicians and patient advocacy organizations with the hope of addressing a serious unmet need and proving that ATTRv can be delayed or prevented
- Acoramidis is approved as Attruby™ by the U.S. FDA and is approved as BEYONTTRA® by the European Commission, Japanese Pharmaceuticals and Medical Devices Agency, and the UK Medicines and Healthcare Products Regulatory Agency

PALO ALTO, Calif., May 13, 2025 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a new type of biopharmaceutical company focused on genetic diseases, announced today that the first asymptomatic participant with a known pathogenic transthyretin (TTR) variant, that may lead to transthyretin amyloid disease (either cardiomyopathy, ATTR-CM, polyneuropathy, ATTR-PN, or both), has been dosed in ACT-EARLY with acoramidis. Acoramidis is a selective, small molecule, orally administered near-complete (≥90%) TTR

stabilizer.

“Launching ACT-EARLY is part of our ongoing commitment to further the genetic understanding of the variants causing ATTR and to ensure patients from around the world have access to optimal care. Our hope is that this study will have profound impact to patients and caregivers, and we look forward to growing our partnership with providers and patient advocacy organizations to establish a new prevention paradigm in an area where there is serious unmet need,” said Adam Castaño, M.D., Vice President of Global Clinical Development at BridgeBio Cardioresenal and Head of the ACT-EARLY clinical program.

ACT-EARLY is the first ever primary prevention study for ATTR, testing the hypothesis that prophylactic treatment of asymptomatic carriers of a pathogenic TTR variant with the near-complete TTR stabilizer, acoramidis, could delay the onset or prevent the development of variant ATTR (ATTRv), also known as hereditary ATTR (hATTR). ATTRv often presents earlier and progresses more aggressively than the wild-type form of ATTR, leading to significantly worse prognosis. The study aims to randomize ~600 asymptomatic carriers of a pathogenic TTR variant. The primary efficacy endpoint is time to development of ATTR-CM and/or ATTR-PN. Additional endpoints include safety and tolerability of acoramidis, and its effects on cardiac imaging parameters, plasma TTR concentration, nerve conduction and neurofilament light chain.

“Current approved therapies for ATTR amyloidosis are only approved to treat diagnosed disease and can only be expected to slow disease progression. There are still many people who carry a genetic variant which puts them at risk of this progressive and fatal disease, and who typically watched other family members suffer through it. Currently, there are no proven prevention treatment options,” said Ahmad Masri, M.D., M.S., Cardiomyopathy Section Head and Director of the Cardiac Amyloidosis Program at Oregon Health & Science University. “By collaborating with BridgeBio on this groundbreaking study, I am hopeful that we can fill the significant gap in care for asymptomatic carriers of a genetic variant by providing potential preventative intervention early with resulting greater clinical benefit than addressing the disease at a later stage.”

In ATTR-CM patients, independent of genotype, the ATTRIBUTE-CM Phase 3 trial showed separation at 3 months in time to first event (all-cause mortality (ACM) or cardiovascular-related hospitalization (CVH)) of acoramidis relative to placebo. In a post-hoc analysis, acoramidis led to a 42% reduction in composite ACM and recurrent CVH events relative to placebo at Month 30. Furthermore, acoramidis showed a 50% reduction in the cumulative frequency of CVH events relative to placebo at Month 30.

At the American College of Cardiology (ACC) 2025 Annual Scientific Sessions & Expo, BridgeBio disclosed that acoramidis achieved statistical significance in reducing the risk of ACM or first CVH versus placebo in the ATTRv-CM (59.1% risk reduction) subgroup. This treatment effect represents the greatest observed benefit to date for ATTRv-CM patients and establishes the mechanistic hypothesis that stabilization of tetrameric TTR with a near-complete

TTR stabilizer, acoramidis, could delay or prevent ATTRv.

"I have met many families of those diagnosed with hereditary ATTR and one question often asked is what can be done for asymptomatic carriers of the genetic variant causing ATTR. Since there is currently no approved therapy to delay or prevent disease onset, this underserved, at-risk population must wait for the development of symptoms before therapy can be prescribed," said Muriel Finkel, President of Amyloidosis Support Groups, a non-profit organization dedicated to the support of amyloidosis patients and caregivers. "I am hopeful that with ACT-EARLY, loved ones of those with variant ATTR will be able to get genetic testing done, and if they meet the qualification criteria, can get started on a clinical trial that might identify whether prophylactic treatment will slow down or prevent ATTR at its genetic source."

Acoramidis is approved as Attruby by the U.S. FDA and is approved as BEYONTTRA by the European Commission, Japanese Pharmaceuticals and Medical Devices Agency, and UK Medicines and Healthcare Products Regulatory Agency with all labels specifying near-complete stabilization of TTR.

ACT-EARLY (NCT06563895) is currently enrolling participants. More information on the study can be found at **ACTEARLY.com**.

About Attruby™ (acoramidis)

INDICATION

Attruby is a transthyretin stabilizer indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

Diarrhea (11.6% vs 7.6%) and upper abdominal pain (5.5% vs 1.4%) were reported in patients treated with Attruby versus placebo, respectively. The majority of these adverse reactions were mild and resolved without drug discontinuation. Discontinuation rates due to adverse events were similar between patients treated with Attruby versus placebo (9.3% and 8.5%, respectively).

About Pharma, Inc.

BridgeBio Pharma, Inc. (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 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

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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. BridgeBio intends 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 the potential for the stabilization of tetrametric TTR to delay the onset or prevent the development of ATTR(v), the expected enrollment of ~600 asymptomatic carriers of a pathogenic TTR variant in the ACT-EARLY study, the Company's expectation to partner globally with ATTR amyloidosis treating physicians and patient advocacy organizations in the ACT-EARLY study, the progress of the ACT-EARLY study, and the potential for the ACT-EARLY study to achieve its endpoints, provide preventative intervention to asymptomatic carriers of ATTR amyloidosis and impact patients and caregivers, among others, reflect BridgeBio's current views about its plans, intentions, expectations and strategies, which are based on the information currently available to BridgeBio and on assumptions BridgeBio has made. Although BridgeBio believes that its plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, BridgeBio 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 the risks associated with BridgeBio's dependence on third parties for development, the risks regulatory authorities may require additional studies or data to support the continued or expanded commercialization of acoramidis, data and results may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review, approval or continued commercialization, other regulatory agencies not agreeing with BridgeBio's regulatory approval strategies, components of BridgeBio's filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, the continuing success of its collaborations, and uncertainty regarding any impacts due to global health emergencies, including delays in regulatory reviews and other regulatory activities, 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 changing interest rates, on BridgeBio's business operations and expectations, as well as those risks set forth in the Risk Factors section of BridgeBio's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q and its other filings with the U.S. Securities and Exchange Commission. Moreover, BridgeBio operates 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 BridgeBio's 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, BridgeBio assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

BridgeBio Media Contact:

Bubba Murarka, EVP Communications

contact@bridgebio.com

(650)-789-8220

BridgeBio Investor Contact:

Chinmay Shukla, VP IR & Strategic Finance

Chinmay.shukla@bridgebio.com

Source: BridgeBio Pharma, Inc.