NEWS RELEASE

acoramidis receives positive chmp opinion for treatment of transthyretin amyloid cardiomyopathy (attr-cm)

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- The Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of acoramidis in the EU based on positive results from the Phase 3 ATTRibute-CM study; final approval decision, typically consistent with the CHMP recommendation, is expected from the European Commission within the coming months
- Acoramidis, a near-complete (≥90%) stabilizer of transthyretin (TTR), was approved on November 22, 2024, by the U.S. Food and Drug Administration (FDA) as Attruby™ to reduce cardiovascular death and cardiovascular-related hospitalization in ATTR-CM; Attruby™ is the first and only approved ATTR-CM treatment in the United States that achieves near-complete stabilization
- In ATTRibute-CM, acoramidis demonstrated the most rapid benefit seen in any Phase 3 study of ATTR-CM to date:
    - In as few as 3 months, the time to first event (all-cause mortality (ACM) or cardiovasacular-related hospitalization (CVH)) durably separated relative to placebo
    - A 42% reduction in composite ACM and recurrent CVH events relative to placebo at Month 30
    - A 50% reduction in the cumulative frequency of CVH events relative to placebo at Month 30
- Relative increases in serum TTR concentrations resulting from greater TTR stability have been associated with reduced risk of all-cause and cardiovascular mortality in the general population in recent literature[1]

PALO ALTO, Calif., Dec. 13, 2024 (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 Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending marketing authorization in the European Union (EU) for acoramidis for the treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). Acoramidis is a selective small molecule, orally administered near-complete (≥90%) transthyretin (TTR) stabilizer. ATTR-CM is a progressive fatal disease that presents as an infiltrative, restrictive cardiomyopathy resulting in heart failure. In the Phase 3 study ATTRibute-CM, acoramidis showed clear benefits on cardiovascular outcomes.

The final approval decision, typically consistent with the CHMP recommendation, is expected from the European Commission in the coming months. Acoramidis was approved by the FDA on November 22, 2024 as Attruby™, the first and only approved product for adults with ATTR-CM in the United States with a label specifying near-complete stabilization of TTR.

The positive CHMP opinion for acoramidis is based on the positive ATTRibute-CM Phase 3 study results. The study investigated the efficacy and safety of acoramidis given twice daily compared with placebo, in subjects with ATTR-CM. The study met its primary clinical endpoints by significantly reducing cardiovascular-related hospitalization, improving survival, and preserving functional capacity and quality of life for patients in need.

“We are encouraged by the CHMP’s positive recommendation of acoramidis and the step forward this represents for the patient community,” said Julie Miller Everett, Chief Business Officer for BridgeBio Cardiovascular. “We are excited to work with Bayer to make acoramidis available to patients in Europe upon approval by the European Commission, which we are looking forward to in early 2025.”

Since March 2024, BridgeBio and Bayer have pursued a collaboration for acoramidis. BridgeBio holds the marketing rights for acoramidis in the U.S., while Bayer holds the marketing rights for the product in Europe. This partnership leverages Bayer’s long legacy of expertise in cardiovascular disease and its established European cardiovascular infrastructure paired with BridgeBio’s leadership in the emerging field of ATTR-CM. Pending European Commission approval, Bayer plans to launch acoramidis in Europe in the first half of 2025.

[1]Christoffersen M et al. Transthyretin Tetramer Destabilization and Increased Mortality in the General Population. JAMA Cardiol. 2024 Dec 4:e244102.

About Attruby™ (acoramidis)
Attruby is the only near-complete (≥90%) stabilizer of Transthyretin (TTR) approved in the U.S. for the treatment of adult patients with ATTR-CM to reduce cardiovascular death and cardiovascular-related hospitalization. Attruby was

generally well-tolerated. The most common side effects were mild and included diarrhea and abdominal pain that were resolved without drug discontinuation. BridgeBio offers an extensive suite of programs to help patients access our medicines.

About BridgeBio

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 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," "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 statements relating to the impact of acoramidis on clinical outcomes, potential benefits of acoramidis, and the potential outcomes and expected timing of regulatory reviews and approvals by the European Medicines Agency and European Commission, 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 commercialization of acoramidis, data and results may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review or approval, 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 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 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 From 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.

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