



## NEWS RELEASE

# beyonttra™ (acoramidis), the first near complete ttr stabilizer ( $\geq 90\%$ ), approved by the european commission to treat attr-cm

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- The approval is based on positive results from the Phase 3 ATTRibute-CM study, in which 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 cardiovascular-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
- Acoramidis is the first and only approved ATTR-CM treatment in the U.S. and EU with a label specifying near-complete stabilization( $\geq 90\%$ )
- 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<sup>1</sup>
- BridgeBio will receive a \$75 million milestone payment from Bayer and will also receive royalties in a tiered

structure beginning in the low-thirties percent on sales of BEYONTTRA in the EU

PALO ALTO, Calif., Feb. 11, 2025 (GLOBE NEWSWIRE) -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), a new type of biopharmaceutical company focused on genetic diseases, today announced the European Commission has granted marketing authorization in the European Union (EU) for acoramidis, under the brand name BEYONTTRA™, 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. Bayer will be responsible for all commercial activity for acoramidis in the EU.

"ATTR-CM is a rapidly progressing disease with a poor prognosis when left untreated, making the approval of acoramidis, which has demonstrated improved benefit on all-cause mortality and cardiovascular-related hospitalizations in as few as three months, a very important accomplishment for patients. We are pleased that people living with ATTR-CM will have access to another treatment option in the EU," 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.

The approval in the EU is based on results of the pivotal ATTRIBUTE-CM Phase 3 study of acoramidis, which showed clear benefits on cardiovascular outcomes. ATTRIBUTE-CM evaluated the efficacy and safety of acoramidis in 632 participants with symptomatic ATTR-CM, associated with either wild-type or variant TTR who were randomized 2:1 to receive acoramidis or placebo for 30 months. The study met its primary clinical endpoints at month 30 by significantly reducing cardiovascular-related hospitalization, improving survival, and preserving functional capacity and quality of life for patients in need.

"The EU approval of acoramidis is a significant advancement for patients living with ATTR-CM in need of new disease-modifying treatments for their condition," said Dr Jonathan Fox, BridgeBio Cardiorenal Chief Medical Officer. "This approval would not have been possible without the commitment of the clinical trial participants and their families, and the dedicated support of the physicians and scientists involved in the clinical program. Alongside our able partners at Bayer we look forward to this new opportunity to serve ATTR-CM patients across the European Union."

Following EU approval, Bayer will launch acoramidis in the first half of 2025. Acoramidis was approved as Attruby™ by the U.S. FDA in November 2024 with a label specifying near-complete stabilization of TTR. As reported on January 13, BridgeBio has seen strong commercial momentum, with 430 patient prescriptions written by 248 physicians

since the U.S. approval.

In March 2024, BridgeBio and Bayer initiated a collaboration for acoramidis, which granted Bayer exclusive commercialization rights in the EU. Based on terms of the licensing agreement, BridgeBio will receive a \$75 million milestone payment upon European Commission approval. BridgeBio will also receive royalties in a tiered structure beginning in the low-thirties percent on sales of acoramidis in the EU following initiation of commercialization efforts.

Acoramidis is currently under review for approval by the Japanese Pharmaceuticals and Medical Devices Agency and the Brazilian Health Regulatory Agency .

<sup>1</sup>Christoffersen M et al. Transthyretin Tetramer Destabilization and Increased Mortality in the General Population. JAMA Cardiol. 2024 Dec 4:e244102.

#### About BEYONTTRA

BEYONTTRA is an orally administered near-complete (≥90%) stabilizer of transthyretin (TTR) indicated for the treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). BEYONTTRA was generally well-tolerated. The most common side effects were mild and included diarrhea and abdominal pain that were resolved without drug discontinuation. For full prescribing information, please refer to the Summary of Product Characteristics (SmPC) which will be available on the European Medicines Agency (EMA) website once published.

#### About BridgeBio 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. 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://bridgebio.com) and follow us on **LinkedIn**, **Twitter** and **Facebook**.

#### 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," "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 BEYONTTRA on clinical outcomes; the potential benefits of BEYONTTRA, including its efficacy and potential to reduce cardiovascular-related hospitalizations, improve survival, and preserve functional capacity and quality of life for patients; and the potential outcomes and expected timing of regulatory reviews and approvals in Japan and Brazil, 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 these 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, manufacture, and commercialization activities related to BEYONTTRA; government and third-party payor actions; risks and uncertainties relating to competitive products and other changes that may limit demand for BEYONTTRA; the risk that regulatory authorities may require additional studies or data to support the continued commercialization of BEYONTTRA; the risk that drug-related adverse events may be observed during commercialization or clinical development; the risk that data and results may not meet regulatory requirements or otherwise be sufficient for further development, regulatory review, or approval; the risk of 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, including compliance with applicable regulations for the purchase, distribution, storage, export, and sale of active pharmaceutical ingredients and medicinal products; 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; and increasing rates of inflation and changing interest rates on BridgeBio's business operations and expectations. These risks, as well as those set forth in the Risk Factors section of BridgeBio's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and its other filings with the U.S. Securities and Exchange Commission, should be carefully considered. Moreover, BridgeBio operates in a highly 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 publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise.

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