



## NEWS RELEASE

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

2025-03-27

- In the Japanese Phase 3 study, 0% mortality was reported over the 30-month treatment period and acoramidis was well-tolerated
- The approval was based on a Japanese Phase 3 study and the global ATTRIBUTE-CM Phase 3 trial, which demonstrated the most rapid benefit seen in any Phase 3 study of ATTR-CM to date. Key data from the ATTRIBUTE-CM study include:
  - 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
- BridgeBio will receive a \$30 million milestone payment from Alexion, AstraZeneca Rare Disease, with royalties in the low double digits on net sales of Beyonttra in Japan

PALO ALTO, Calif., March 27, 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 Japanese Ministry of Health, Labour and Welfare has approved acoramidis, under the brand name Beyonttra, for the treatment of adults with transthyretin-mediated amyloid cardiomyopathy (ATTR-CM). Acoramidis is a selective small molecule, orally administered, near-complete ( $\geq 90\%$ ) transthyretin (TTR) stabilizer. 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> ATTR-CM is a progressive, fatal disease that

presents as an infiltrative, restrictive cardiomyopathy resulting in heart failure. Alexion, AstraZeneca Rare Disease will be responsible for all commercial activity for Beyonttra in Japan.

“There is significant need for new treatment options for ATTR-CM, a progressive, fatal disease, worldwide. This latest approval marks an important development for the ATTR-CM community, and we are pleased that patients living with this condition in Japan now have a new treatment option that offers early and sustained reductions in cardiovascular events,” said Dr. Jonathan Fox, BridgeBio Cardiorenal Chief Medical Officer.

The approval in Japan is based on positive results from a Phase 3 open-label, single-arm study conducted in Japan by Alexion, AstraZeneca Rare Disease, and the positive results from the global ATTRIBUTE-CM Phase 3 study. In the Japanese trial, acoramidis was generally well tolerated and 0% mortality was reported during the 30-month acoramidis treatment period. BridgeBio’s global ATTRIBUTE-CM Phase 3 trial showed early separation at 3 months in time to first event (ACM or CVH) durably separated relative to placebo. Furthermore, within the global ATTRIBUTE-CM trial acoramidis led to a 42% reduction in composite ACM and recurrent CVH events relative to placebo at Month 30, as well as a 50% reduction in the cumulative frequency of CVH events relative to placebo at Month 30.

Alexion, AstraZeneca Rare Disease, maintains an exclusive license with BridgeBio’s affiliate, Eidos Therapeutics, Inc. to develop and commercialize acoramidis in Japan. Based on the terms of the agreement, BridgeBio will receive a \$30 million milestone payment upon approval in Japan, as well as royalties in the low double digits on sales of acoramidis in Japan, with commercialization efforts planned in the first half of 2025.

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

#### Beyonttra (acoramidis)

Beyonttra is an orally administered near-complete ( $\geq 90\%$ ) stabilizer of transthyretin (TTR) indicated for the treatment of wild-type or variant transthyretin amyloid cardiomyopathy (ATTR-CM) in adults. Beyonttra was generally well-tolerated. Please refer the Japanese Prescribing Information as made available by the PMDA for Japanese specific safety labelling. In the US prescribing information, where acoramidis is approved under the brand name Attriby™, the most common side effects were mild and included diarrhea and abdominal pain that were resolved without drug discontinuation.

Alexion maintains an exclusive license with BridgeBio’s affiliate, Eidos Therapeutics, Inc., to develop and commercialize Beyonttra in Japan.

#### 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 Beyontra on clinical outcomes; and the potential benefits of Beyontra, including its efficacy and potential to reduce ACM or CVH events, 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 Beyontra; government and third-party payor actions; risks and uncertainties relating to competitive products and other changes that may limit demand for Beyontra; the risk that regulatory authorities may require additional studies or data to support the continued commercialization of Beyontra; 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 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.

BridgeBio Media Contact:

Bubba Murarka, EVP Communications

**contact@bridgebio.com**

(650)-789-8220