



NEWS RELEASE

BEYONTTRA® (acoramidis), the First Near-complete TTR Stabilizer ($\geq 90\%$), Approved by the UK Medicines and Healthcare Products Regulatory Agency to Treat ATTR-CM

2025-04-28

- The UK 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., EU, UK and Japan that all have 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 literature¹

- BridgeBio will receive royalties in a tiered structure beginning in the low-thirties percent on sales of Beyontra in the UK

PALO ALTO, Calif., April 28, 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 Medicines and Healthcare products Regulatory Agency has granted marketing authorization in the United Kingdom (UK) 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 UK.

"ATTR-CM is a progressive and debilitating disease that poses significant challenges not only for patients but also for the healthcare systems. The condition profoundly impacts patients' quality of life. Symptoms attributable to amyloidosis are usually nonspecific, varied and associated with low awareness, frequently resulting in delayed or completely missed diagnosis,² which may lead to delayed treatment and a worse prognosis. In the absence of intervention, ATTR-CM causes progressive heart failure leading to increased hospitalizations and escalating healthcare costs and is ultimately fatal,³⁻⁵" said Julian Gillmore, M.D., Ph.D., University College London's Centre for Amyloidosis, UK. "The UK authorization of Beyontra is welcome news for eligible patients living with the condition. Physicians in the UK now have another treatment option to slow the progression of symptoms and improve outcomes for patients with ATTR-CM."

The approval in the UK 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.

"We are proud to add another approval for acoramidis and thrilled that patients in the UK will now have access to BEYONTTRA since they are in great need of new disease-modifying treatments for their condition," said Jonathan Fox, M.D., Ph.D., President and Chief Medical Officer of BridgeBio Cardiorenal. "We appreciate the time and commitment of every clinical trial participant and their families, and the dedicated support of the physicians and scientists involved in the clinical program. This important milestone would not have been possible without their commitment to the program. We look forward to extending our collaboration with our European partner, Bayer, to serve ATTR-CM patients across the UK and the rest of Europe, and will continue to work towards reaching patients in as many regions as possible around the world."

Acoramidis was approved as Attruby[™] by the U.S. FDA in November 2024 and was approved as BEYONTTRA by the European Commission in February 2025 and the Japanese Ministry of Health, Labour, and Welfare (MHLW) Agency

in March 2025 with all labels specifying near-complete stabilization of TTR.

In March 2024, BridgeBio and Bayer initiated a collaboration for acoramidis, which granted Bayer exclusive commercialization rights in Europe. Based on terms of the licensing agreement, BridgeBio will receive royalties in a tiered structure beginning in the low-thirties percent on sales of acoramidis in the UK following initiation of commercialization efforts.

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

²Rintell et al. Orphanet J Rare Dis. (2021) 16:70. <https://doi.org/10.1186/s13023-021-01706-7>

³Rozenbaum MH, et al. Impact of delayed diagnosis and misdiagnosis for patients with transthyretin amyloid cardiomyopathy (ATTR-CM): a targeted literature review. Cardiology and therapy. 2021;10:141-59.

⁴Mallus MT and Rizzello V. Treatment of amyloidosis: present and future. 2023;21;25(Suppl B):B99-B103.

⁵Jain A, Zahra F. Transthyretin Amyloid Cardiomyopathy (ATTR-CM). Updated 27 April 2023. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from:

<https://www.ncbi.nlm.nih.gov/books/NBK574531/> Last accessed: March 2025.

About BEYONTTRA

BEYONTTRA is an orally administered near-complete ($\geq 90\%$) stabilizer of transthyretin (TTR) indicated for the treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM). For full prescribing information, please refer to the Summary of Product Characteristics (SmPC) on the Medicines and Healthcare products Regulatory Agency website at <https://products.mhra.gov.uk/>.

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).

▼: This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

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," "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; and the potential benefits of Beyonttra, including its ability to reduce cardiovascular-related hospitalization, improve survival, and preserve functional capacity and quality of life, 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 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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