

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 17, 2023

**BridgeBio Pharma, Inc.**  
(Exact name of Registrant as Specified in Its Charter)

Delaware  
(State or other jurisdiction of incorporation)

001-38959  
(Commission File Number)

84-1850815  
(IRS Employer Identification No.)

3160 Porter Dr., Suite 250  
Palo Alto, CA  
(Address of principal executive offices)

94304  
(Zip Code)

Registrant's telephone number, including area code: (650) 391-9740

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	BBIO	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

On July 17, 2023, BridgeBio Pharma, Inc. (the “Company”) issued a press release announcing positive data from its Phase 3 ATTRIBUTE-CM clinical trial of acoramidis for patients with transthyretin amyloid cardiomyopathy (ATTR-CM), a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K. The Company intends to host a conference call and live webcast to discuss the clinical data on July 17, 2023 at 8:00 a.m. E.T. The Company has made available a slide presentation to accompany the call, a copy of which is being furnished as Exhibit 99.2 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

The information in this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 attached hereto, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 8.01 Other Events.**

On July 17, 2023, the Company announced positive data from its Phase 3 ATTRIBUTE-CM clinical trial of acoramidis for patients with transthyretin amyloid cardiomyopathy (ATTR-CM).

Key results from the clinical trial include:

- A highly statistically significant improvement in the primary endpoint (a hierarchical analysis prioritizing in order: all-cause mortality, then frequency of cardiovascular-related hospitalization, then change from baseline in NT-proBNP, then change from baseline in 6-minute walk distance) demonstrated by a Win Ratio of 1.8 ( $p < 0.0001$ ).
- An 81% on-treatment survival rate (versus a 74% survival rate on placebo), which begins to approach actuarial models of life expectancy absent ATTR-CM (85% in this population as has been documented). The absolute risk reduction was 6.43% and the relative risk reduction was 25%.
- A highly statistically significant relative risk reduction of 50% ( $p < 0.0001$ ) on frequency of cardiovascular-related hospitalization. The impact and marked magnitude of risk reduction was seen across all analytical methods employed.
- The Company consistently observed a statistically significant treatment effect at 30 months across additional measured markers of morbidity, quality of life, and function:
  - Change from baseline in N-terminal prohormone of brain natriuretic peptide (NT-proBNP) ( $p < 0.0001$ )
  - Change from baseline in Kansas City Cardiomyopathy Questionnaire ( $p < 0.0001$ )
  - Change from baseline in 6-minute walk distance ( $p < 0.0001$ )
- No safety signals of potential clinical concern were identified.

**Cautionary Note Regarding Forward Looking Statements**

This Current Report on Form 8-K and certain of the materials filed and furnished herewith contain forward-looking statements. Statements in this Current Report on Form 8-K or the materials furnished or filed herewith may include statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act, which are usually identified by the use of words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “will,” and variations of such words or similar expressions. The Company 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 clinical, therapeutic and market potential of the Company’s programs and product candidates, including its clinical development program for acoramidis for patients with transthyretin amyloid cardiomyopathy, the timing and success of its clinical development programs, the progress of its ongoing and planned clinical trials of acoramidis for patients with transthyretin amyloid cardiomyopathy, including its plans to file a new NDA with the FDA by end of year 2023, its planned interactions with regulatory authorities, the availability of data from its clinical trials of acoramidis, and the timing of these events, reflect its current views about its plans, intentions, expectations and strategies, which are based on the information currently available to the Company and on assumptions it has made. Although the Company believes that its plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, it 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, initial and ongoing data from the Company’s clinical trials not being indicative of final data, the design and success of ongoing and planned clinical trials, difficulties with enrollment in its clinical trials, adverse events that may be encountered in its clinical trials, the FDA or other regulatory agencies not agreeing with its regulatory approval strategies, components of its filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, potential adverse impacts due to the global COVID-19 pandemic such as 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 the COVID-19 pandemic, hostilities in Ukraine, increasing rates of inflation and rising interest rates, on its overall business operations and expectations, as well as those risks set forth in the Risk Factors section of its Annual Report on Form 10-K for the year ended December 31, 2022 and its other filings with the U.S. Securities and Exchange Commission. Moreover, the Company 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 the Company’s management as of the date of this Current Report on Form 8-K, 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, the Company assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

**Item 9.01 Financial Statements and Exhibits.**

[99.1](#) Press release issued by BridgeBio Pharma, Inc. on July 17, 2023, furnished herewith.

[99.2](#) Corporate presentation, dated July 17, 2023, furnished herewith.

104 Cover Page Interactive Data File (embedded within Inline XBRL document)

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**BRIDGEBIO PHARMA, INC.**

Date: July 17, 2023

By: /s/ Brian C. Stephenson  
Brian C. Stephenson  
Chief Financial Officer

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**BridgeBio announces consistently positive results from Phase 3 ATTRibute-CM study of acoramidis for patients with transthyretin amyloid cardiomyopathy (ATTR-CM)**

- *Highly statistically significant result observed on primary endpoint with a Win Ratio of 1.8 ( $p < 0.0001$ )*
- *58% of ties in Finkelstein-Schoenfeld (F-S) primary analysis broken by all-cause mortality and frequency of cardiovascular-related hospitalization; statistical significance also achieved on an F-S test with those two parameters alone ( $p = 0.0182$ )*
  - *Clinically meaningful and consistent separation observed on all measures of mortality, morbidity, function, and quality of life*
  - *On-treatment survival rate of 81% versus placebo survival rate of 74% (absolute risk reduction of 6.43%; relative risk reduction of 25%)*
  - *Highly statistically significant relative risk reduction of 50% ( $p < 0.0001$ ) observed on frequency of cardiovascular-related hospitalization*
- *Highly statistically significant and clinically meaningful treatment benefit observed at 30 months on the secondary endpoints of NT-proBNP ( $p < 0.0001$ ), KCCQ ( $p < 0.0001$ ), and 6-minute walk distance ( $p < 0.0001$ )*
- *In comparative exploratory post hoc analyses enabled by tafamidis drop-in, albeit at low patient numbers, acoramidis showed 42% greater increase in serum TTR levels and a 92% improvement in median NT-proBNP relative to placebo + tafamidis*
  - *No safety signals of potential clinical concern identified*
- *Company intends to file a New Drug Application (NDA) with the U.S. Food and Drug Administration by end of 2023; late-breaker presentation has been accepted for annual meeting of the European Society of Cardiology*

**PALO ALTO, Calif., July 17, 2023 (GLOBE NEWSWIRE)** -- BridgeBio Pharma, Inc. (Nasdaq: BBIO) ("BridgeBio" or the "Company"), is a commercial-stage biopharmaceutical company focused on genetic diseases and cancers. Today, alongside the dedicated physicians and courageous patients who participated, the Company reports positive results from ATTRibute-CM, its Phase 3 study of acoramidis in transthyretin amyloid cardiomyopathy, or ATTR-CM. ATTRibute-CM was designed to study the efficacy and safety of acoramidis, an investigational, next-generation, orally-administered, highly potent, small molecule stabilizer of transthyretin (TTR). BridgeBio will host an [investor call](#) on July 17, 2023 at 8:00 am ET to discuss these results.

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“The outstanding results of the ATTRibute-CM study provide new hope to patients living with transthyretin amyloid cardiomyopathy, or ATTR-CM”, said Dr. Daniel Judge, Professor of Medicine and Cardiology at the Medical University of South Carolina, and Co-Chair of the ATTRibute-CM Steering Committee. “The consistent and clinically meaningful benefits on survival, hospitalization, and additional measures of illness severity are truly remarkable.”

“ATTR-CM is an increasingly recognized cause of heart failure. The results from BridgeBio’s ATTRibute-CM trial are very exciting and bring much hope to amyloidosis patients and their loved ones,” said Muriel Finkel, President of Amyloidosis Support Groups, a non-profit organization dedicated to the support of amyloidosis patients and caregivers.

Key results from the clinical trial include:

- A highly statistically significant improvement in the primary endpoint (a hierarchical analysis prioritizing in order: all-cause mortality, then frequency of cardiovascular-related hospitalization, then change from baseline in NT-proBNP, then change from baseline in 6-minute walk distance) demonstrated by a Win Ratio of 1.8 ( $p < 0.0001$ ).
- An 81% on-treatment survival rate (versus a 74% survival rate on placebo), which begins to approach actuarial models of life expectancy absent ATTR-CM (85% in this population as has been documented). The absolute risk reduction was 6.43% and the relative risk reduction was 25%.
- A highly statistically significant relative risk reduction of 50% ( $p < 0.0001$ ) on frequency of cardiovascular-related hospitalization. The impact and marked magnitude of risk reduction was seen across all analytical methods employed.
- The Company consistently observed a statistically significant treatment effect at 30 months across additional measured markers of morbidity, quality of life, and function:
  - Change from baseline in N-terminal prohormone of brain natriuretic peptide (NT-proBNP) ( $p < 0.0001$ )
  - Change from baseline in Kansas City Cardiomyopathy Questionnaire ( $p < 0.0001$ )
  - Change from baseline in 6-minute walk distance ( $p < 0.0001$ )
- No safety signals of potential clinical concern were identified.

A key objective in the rational drug design of acoramidis was to maximize TTR stabilization at clinically achieved blood concentrations. Several lines of evidence suggest that maximizing stabilization could lead to improved benefits for ATTR patients:

- Historical ATTR genotype/phenotype data and the disease-protective properties of trans-allelic, trans-suppressor variants relative to pathogenic variants in compound heterozygotes and the general, nonvariant population
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- The outperformance of 80mg tafamidis vs 20mg tafamidis in the previously published ATTR-ACT trial
- Results from ATTR-polyneuropathy clinical trials

BridgeBio's design strategy to maximize TTR stabilization by acoramidis was to phenocopy the hyperstabilizing molecular mechanism of the T119M trans-allelic, trans-suppressor rescue mutation. Prior preclinical and clinical studies have shown that acoramidis demonstrates approximately twice the stabilization of already-marketed stabilizers.

The allowance of tafamidis drop-in after at least 12 months in both the placebo and the acoramidis arms of the ATTRibute-CM trial provided the Company an opportunity to analyze, in an exploratory post hoc fashion and albeit at low patient numbers, differences in stabilizer performance as measured by serum TTR and NT- proBNP. The findings at 30 months were that:

- Acoramidis showed a 42% greater increase in serum TTR levels versus tafamidis
- Acoramidis showed a 92% improvement in median NT-proBNP relative to placebo + tafamidis

No comparison can be made as to the potential effectiveness or safety of acoramidis and tafamidis, given that these are exploratory analyses and the study was not prospectively designed for a head-to-head comparison.

"Our heartfelt thanks go out to the patients, their caregivers, investigators, and study staff who have actively participated in ATTRibute-CM and continue to contribute to this pivotal research," stated Jonathan Fox, M.D., Ph.D., President and Chief Medical Officer of BridgeBio Cardiorenal. "We are extremely encouraged by the robustly positive and consistent findings of the ATTRibute-CM study, which confirm our position that highly potent TTR stabilization has the potential to profoundly impact patients' lives. We look forward to presenting the data to health authorities to bring acoramidis to patients as expeditiously as possible."

The Company intends to submit its NDA to the US FDA before the end of 2023, with regulatory filings in additional markets to follow in 2024. This activity will occur in parallel with the prosecution of the remainder of the BridgeBio portfolio, which like acoramidis consists of medicines that target well-described diseases at their source. Acoramidis has intellectual property protection out to at least 2039.

#### **Webcast Information**

BridgeBio will host an investor call and simultaneous webcast to discuss the results from the Phase 3 ATTRibute-CM study of acoramidis in patients with ATTR-CM on July 17, 2023, at 8:00 am ET. A link to the webcast may be accessed from the event calendar page of BridgeBio's website at <https://investor.bridgebio.com/>. A replay of the conference call and webcast will be archived on the Company's website and will be available for at least 30 days following the event.

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## About BridgeBio Pharma, Inc.

BridgeBio Pharma, Inc. (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](https://www.bridgebio.com) and follow us on [LinkedIn](#) and [Twitter](#).

### 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," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "continue," "will," and variations of such words or similar expressions. We intend 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 clinical, therapeutic and market potential of our programs and product candidates, including our clinical development program for acoramidis for patients with transthyretin amyloid cardiomyopathy, the timing and success of our clinical development programs, the progress of our ongoing and planned clinical trials of acoramidis for patients with transthyretin amyloid cardiomyopathy, including our plans to file a new NDA with the FDA by end of year 2023, our planned interactions with regulatory authorities, the availability of data from our clinical trials of acoramidis, and the timing of these events, reflect our current views about our plans, intentions, expectations and strategies, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations and strategies as reflected in or suggested by those forward-looking statements are reasonable, we 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, initial and ongoing data from our clinical trials not being indicative of final data, the design and success of ongoing and planned clinical trials, difficulties with enrollment in our clinical trials, adverse events that may be encountered in our clinical trials, the FDA or other regulatory agencies not agreeing with our regulatory approval strategies, components of our filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of data submitted, potential adverse impacts due to the global COVID-19 pandemic such as 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 the COVID-19 pandemic, hostilities in Ukraine, increasing rates of inflation and rising interest rates, on our overall business operations and expectations, as well as those risks set forth in the Risk Factors section of our Annual Report on Form 10-K for the year ended December 31, 2022 and our other filings with the U.S. Securities and Exchange Commission. Moreover, we operate 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 our 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, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

### BridgeBio Contact:

Vikram Bali  
contact@bridgebio.com  
(650)-789-8220

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bridgebio

hope through  
rigorous science

# ATTRIBUTE-CM Phase 3 Topline Results

July 17, 2023





# Forward-Looking Statements and Disclaimer

The presentation at the call may contain forward-looking statements. Statements made or presented at the call 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, and Section 21E of the Securities Exchange Act of 1934, as amended. Words such as “believe,” “anticipate,” “plan,” “expect,” “intend,” “will,” “may,” “goal,” “potential,” “should,” “could,” “aim,” “estimate,” “predict,” “continue” and similar expressions or the negative of these terms or other comparable terminology are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. We intend 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 clinical, therapeutic and market potential of our programs and product candidates, including our clinical development program for acoramidis for patients with transthyretin amyloid cardiomyopathy, the timing and success of our clinical development programs, the progress of our ongoing and planned clinical trials of acoramidis for patients with transthyretin amyloid cardiomyopathy, including our plans to file a new NDA with the FDA by end of year 2023, our planned interactions with regulatory authorities, the availability of data from our clinical trials of acoramidis, and the timing of these events, reflect our current views about our plans, intentions, expectations and strategies, which are based on the information currently available to us and on assumptions we have made. Such statements reflect the current views of the Company with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about the Company, including, without limitation, risks inherent in developing therapeutic products, and those risks and uncertainties described under the heading “Risk Factors” in the Company’s most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) and in subsequent filings made by the Company with the SEC, which are available on the SEC’s website at [www.sec.gov](http://www.sec.gov). In light of these risks and uncertainties, many of which are beyond the Company’s control, the events or circumstances referred to in the forward-looking statements, express or implied, may not occur. The actual results may vary from the anticipated results and the variations may be material. You are cautioned not to place undue reliance on these forward-looking statements, which speak to the Company’s current beliefs and expectations only as of the date of the call. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements made or presented at the call in the event of new information, future developments or otherwise. No representation is made as to the safety or effectiveness of the product candidates for the therapeutic use for which such product candidates are being studied.

Certain information communicated at the call may relate to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company’s own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of the call, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, certain information to be communicated at the call involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, such research has not been verified by any independent source.

Such information is provided as of the date of the call and is subject to change without notice. The Company has not verified, and will not verify, any part of this presentation, and the Company makes no representation or warranty, express or implied, as to the accuracy or completeness of the information to be communicated at the call or as to the existence, substance or materiality of any information omitted from the presentation at the call. The Company disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this document or the related presentation and such liability is expressly disclaimed.

## Discussion topics

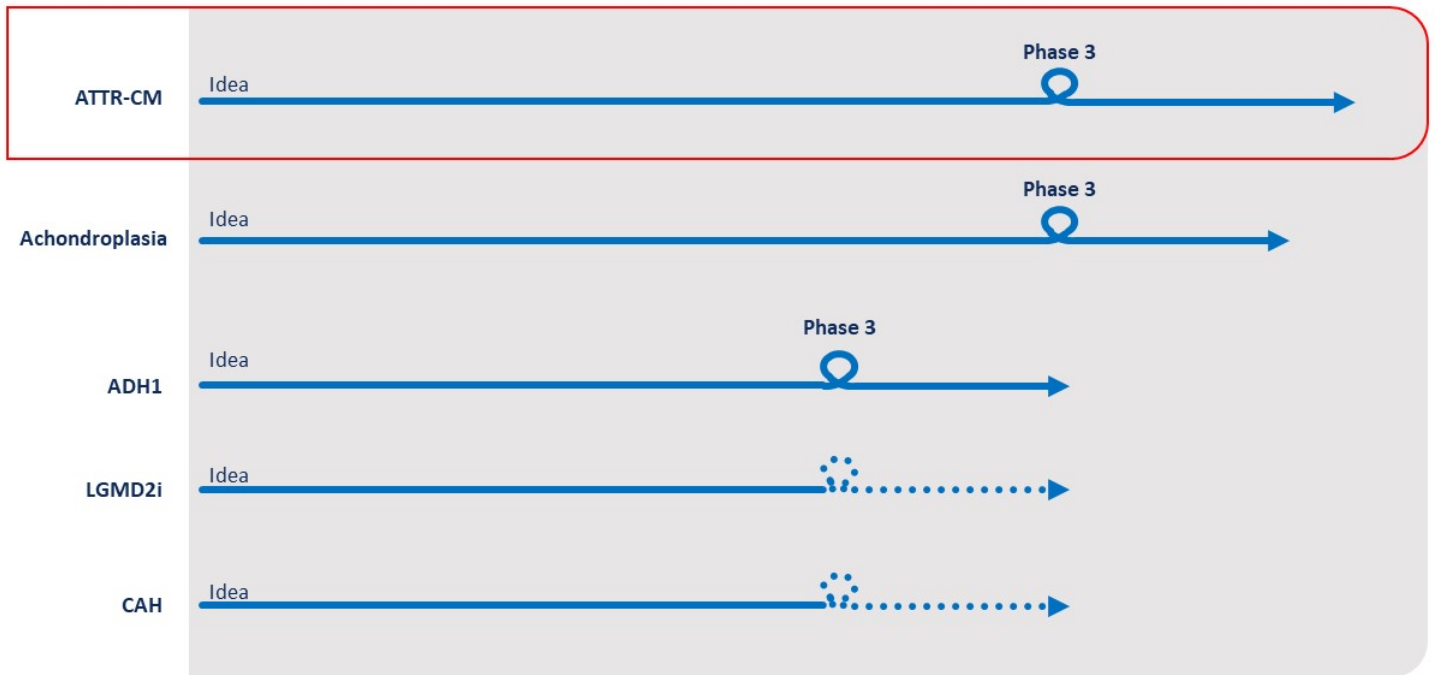
1	Introduction & Overview	Neil Kumar, PhD Chief Executive Officer
2	ATTRIBUTE-CM Phase 3 Topline Results	Jonathan Fox, MD, PhD Chief Medical Officer, Cardiorenal
3	Next Steps	Uma Sinha, PhD Chief Scientific Officer
4	Commercial Launch Plans	Matt Outten, MBA Chief Commercial Officer
5	Q&A Session	



*(acoramidis for ATTR-CM)*

***A sincere THANK YOU to patients and families, advocates, physicians,  
clinical research staff, and collaborating research partners***

# Program context



# Acoramidis was designed to achieve maximal stabilization and preserve native TTR

## Design Objectives

**1 Maximize TTR stabilization/minimize toxic monomer**

## Rationale

- Strong genotype/phenotype correlation between TTR instability and disease severity<sup>1</sup>
- Dose-dependent improvements in both TTR stabilization and clinical outcomes demonstrated by tafamidis in ATTR-CM<sup>2</sup>
- Extent of TTR stabilization or knockdown associated with degree of clinical benefit in ATTR-PN<sup>3-6</sup>

**2 Preserve circulating native TTR**

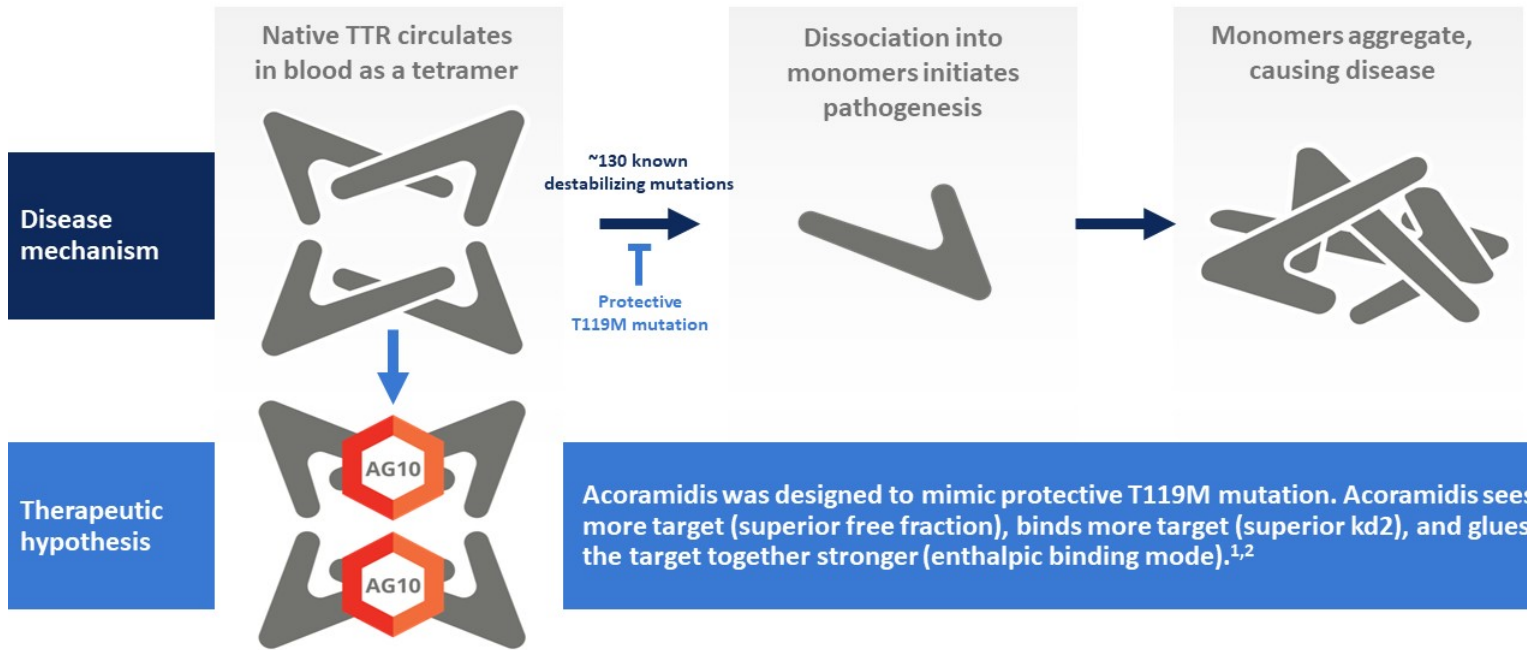
- TTR has been highly conserved throughout evolution<sup>7</sup>
- TTR is an abundant plasma protein with relatively rapid turnover requiring sustained metabolic energy expenditure

**We plan to enter the ATTR-CM market with acoramidis, a next generation, more potent TTR stabilizer**

TTR = Transthyretin; ATTR-CM = TTR amyloid cardiomyopathy.

<sup>1</sup>Hammarstrom, P et al., PNAS. 2002;99:16427-16432. <sup>2</sup>Damy, T., et al., Eur J Heart Fail. 2021;23(2):277-285. <sup>3</sup>Coelho, T. et al., Neurology. 2012;79:785-792. <sup>4</sup>Berk, JL et al., JAMA. 2013;310:2658-2667. <sup>5</sup>Adams, DA. et al., N Engl J Med. 2018;379:11-21. <sup>6</sup>Benson, M.D., et al., N Engl J Med. 2018;379:22-31. <sup>7</sup>Richardson SJ, et al. Front Endocrinol. 2015;5:1-9.

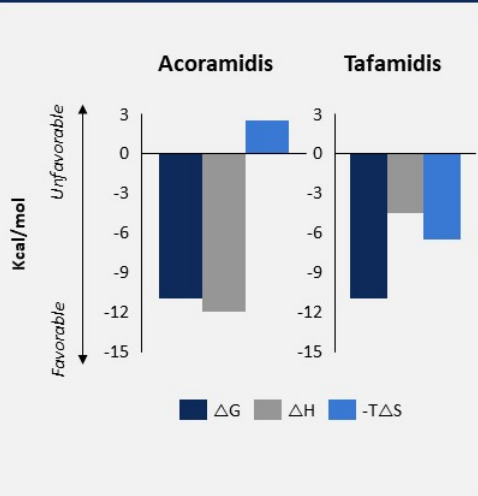
# Acoramidis is a next generation stabilizer that employs multiple strategies to maximize potency



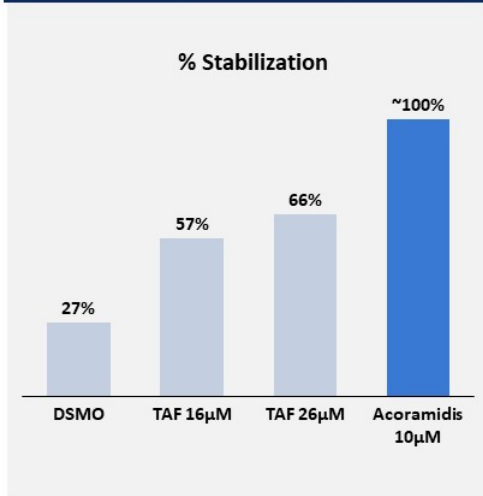
Acoramidis is an investigational molecule. The safety and efficacy have not been established by regulatory authorities.  
<sup>1</sup>Data on File. <sup>2</sup>Miller, M. et al. J Med Chem. 2018;61:7862-7876.

# Data supporting more potent TTR stabilization

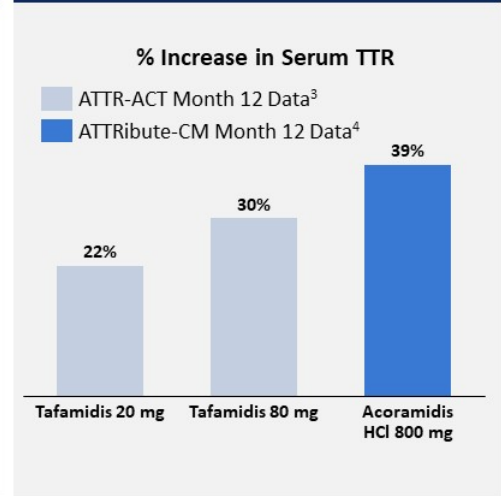
## Superior Binding to TTR in vitro<sup>1</sup> facilitated by enthalpic interactions



## Near-Complete TTR Stabilization<sup>2</sup> at target trough clinical concentrations



## Rapid, durable increases in serum TTR an in vivo marker of native tetramer stability



<sup>1</sup>Miller, M. et al. J Med Chem. 2018;61:7862-7876. <sup>2</sup>Ji, A.X., et al. American Heart Association Scientific Sessions, 2019. <sup>3</sup>Estimated from Damy, T., et al., Eur J Heart Fail. 2021;23(2):277-285. <sup>4</sup>BridgeBio Part A press release, December 27, 2021.

Note: Direct cross-study comparisons may suggest misleading similarities or differences. The values shown are directional and do not report robust comparative analysis.

# Unprecedented and consistent benefit on survival and morbidity

## Best Case Target Clinical Profile

**Achieve statistical significance on primary endpoint:**  
p-value <0.04

**Unprecedented survival:** Highest ever 30-month survival rate on drug (>80%) with clinically meaningful separation from placebo

**Best-in-class CVH data:** Profound reduction in event rates

**Win Ratio better than 1.7:** Significant impact on mortality and morbidity

**Best-in-class treatment effect on serum biomarkers:** NT-proBNP, serum TTR, TTR stabilization

## Outcome Observed

✓ Primary endpoint met (p<0.0001)

✓ 81% 30-month survival on acoramidis  
✓ 6.4% absolute & 25% relative risk reduction compared to placebo

✓ 50% relative risk reduction for cumulative frequency of CVH (p<0.0001)

✓ Win Ratio = 1.8

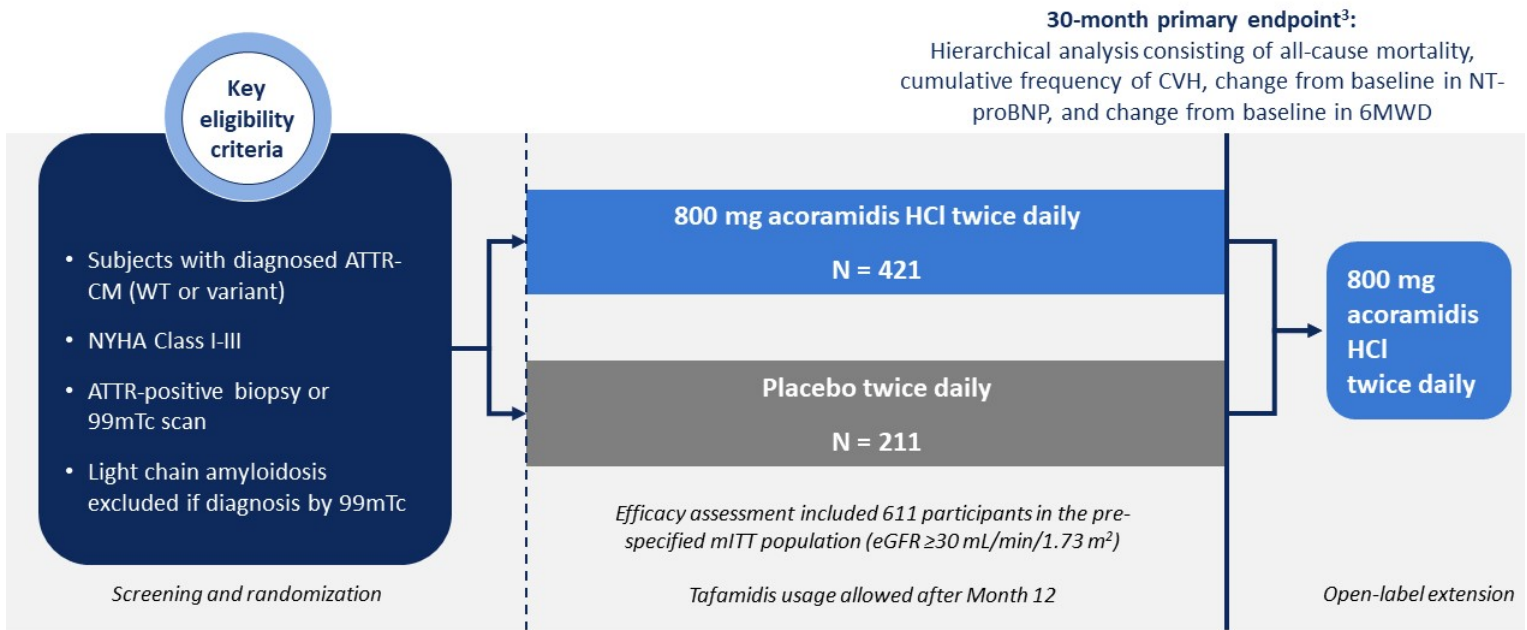
✓ Clinically and statistically significant (p<0.0001) benefit on NT-proBNP and serum TTR; sustained impact on TTR stabilization



## Discussion topics

1	Introduction & Overview	Neil Kumar, PhD Chief Executive Officer
2	<b>ATTRIBUTE-CM Phase 3 Topline Results</b>	Jonathan Fox, MD, PhD Chief Medical Officer, Cardiorenal
3	Next Steps	Uma Sinha, PhD Chief Scientific Officer
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5	Q&A Session	

# ATTRibute-CM study design<sup>1,2</sup>



6MWD = Six-minute walk distance; NYHA = New York Heart Association; 99mTc = Technetium labeled pyrophosphate (PYP) or bisphosphonate (e.g., DPD); mITT = Modified intent-to-treat. eGFR = Estimated glomerular filtration rate.

<sup>1</sup>ClinicalTrials.gov identifier: NCT03860935. <sup>2</sup>Gillmore JD et al. Circulation. 2019;140(1):142-154. Oral poster presented at AHA. <sup>3</sup>Primary analysis assessed using the Finkelstein-Schoenfeld method.

# Highly statistically significant result achieved on primary and select secondary endpoints

Primary endpoint <sup>1</sup>	p-value
Hierarchical analysis consisting of:	
<ul style="list-style-type: none"> <li>All-cause mortality<sup>2</sup></li> <li>Cumulative frequency of CVH</li> <li>Change from baseline in NT-proBNP</li> <li>Change from baseline in 6MWD</li> </ul>	p<0.0001
Win Ratio	1.8
Select secondary endpoints	p-value
Cumulative frequency of CVH <sup>3</sup>	p<0.0001
Change from baseline in 6MWD <sup>4</sup>	p<0.0001
Change from baseline in KCCQ-OS <sup>4</sup>	p<0.0001
Change from baseline in serum TTR <sup>4</sup>	p<0.0001
Change from baseline in NT-proBNP <sup>5</sup>	p<0.0001
All-cause mortality <sup>2,6</sup>	p=0.057

58% of ties broken by first two components of Win Ratio analysis

KCCQ-OS = Kansas City cardiomyopathy questionnaire overall summary score.

<sup>1</sup>Primary analysis assessed using the Finkelstein-Schoenfeld method. <sup>2</sup>Heart transplant and implantation of cardiac mechanical assistance device were treated as death for this analysis. <sup>3</sup>Negative binomial regression with treatment group, stratification factors and the offset term is used to analyze the cumulative frequency of adjudicated CV-related hospitalization. <sup>4</sup>Least squares mean difference change from baseline at 30 months. <sup>5</sup>Ratio of adjusted geometric mean fold change from baseline at 30 months. <sup>6</sup>Assessed by Cochran-Mantel-Haenszel test; p=0.15 as assessed by Cox Proportional Hazard Model.

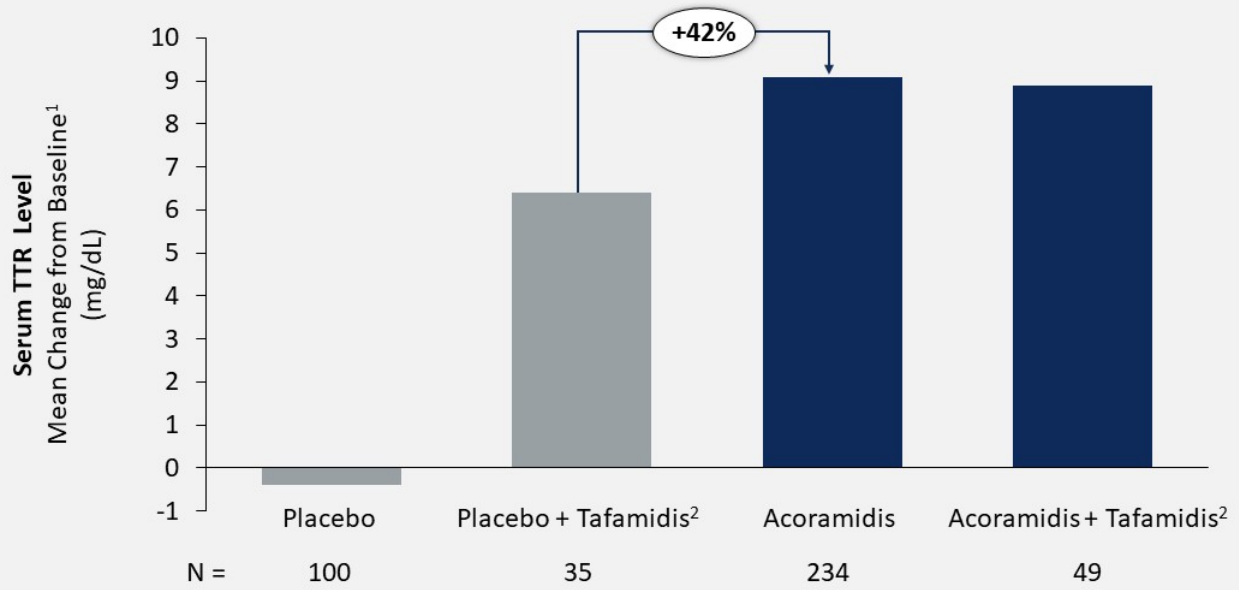
## No safety signals of potential clinical concern identified

Subjects with one or more event(s)	Acoramidis N=421 N (%)	Placebo N=211 N (%)
Any treatment-emergent adverse events (TEAEs)	413 (98.1%)	206 (97.6%)
TEAE with fatal outcome	60 (14.3%)	36 (17.1%)
TEAE leading to hospitalization	212 (50.4%)	128 (60.7%)
TEAE leading to study drug discontinuation	39 (9.3%)	18 (8.5%)
Any treatment-emergent serious adverse events (SAEs)	230 (54.6%)	137 (64.9%)
Treatment-emergent SAEs leading to study drug discontinuation	21 (5.0%)	15 (7.1%)
Severe TEAEs <sup>1</sup>	157 (37.3%)	96 (45.5%)

All Adverse Events (AEs) occurring during the treatment period are considered treatment-emergent adverse events (TEAEs). Serious Adverse Event (SAE) meets seriousness criteria.

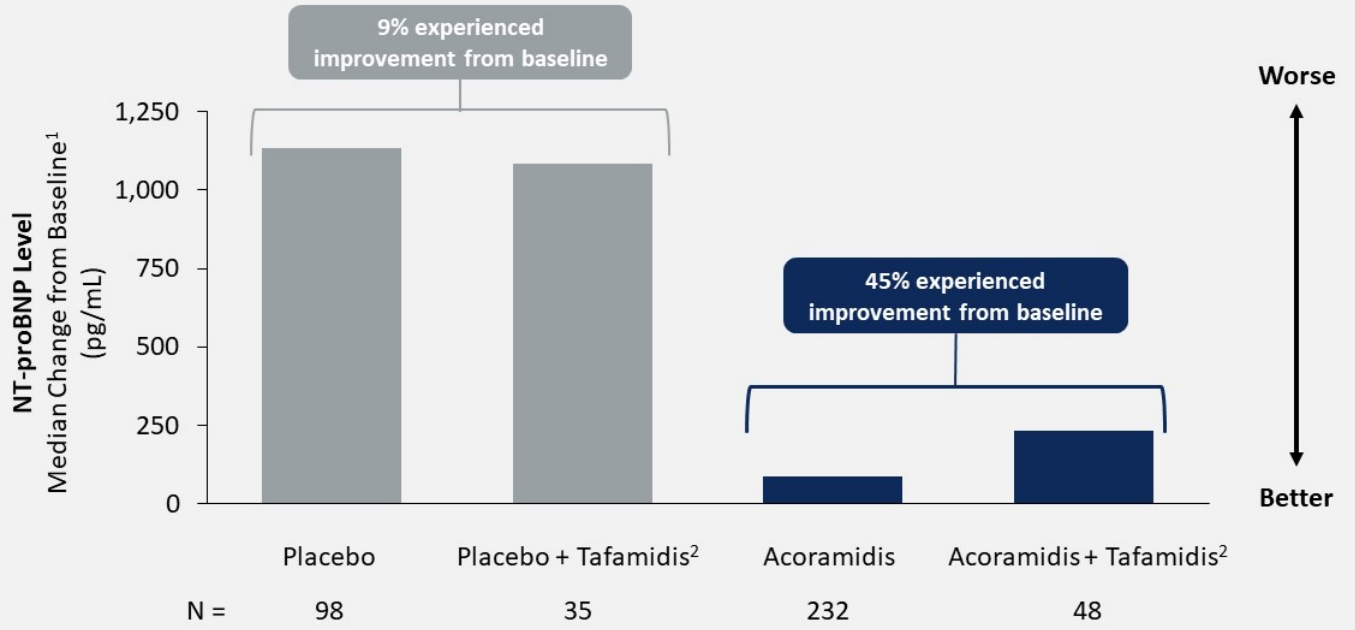
<sup>1</sup>Severity as assessed by the investigator.

## Exploratory post hoc analysis: serum TTR levels



<sup>1</sup>Mean change from baseline in serum TTR at Month 30 in mITT population. <sup>2</sup>Mean exposure on tafamidis = 11 months in mITT population.

# Exploratory post hoc analysis: median NT-proBNP



<sup>1</sup>Median change from baseline in NT-proBNP at Month 30 in mITT population. <sup>2</sup>Mean exposure on tafamidis = 11 months in mITT population.

## Summary of topline results

**Acoramidis was observed to consistently outperform placebo on survival and established measures of ATTR-CM morbidity**

- ✓ Unprecedented **30-month survival of >80%** for a targeted intervention in ATTR-CM
- ✓ Achieved primary endpoint with highly statistically significant result with **Win Ratio of 1.8**
- ✓ **6.4% ARR & 25% RRR** in all-cause mortality
- ✓ **50% RRR** for cumulative frequency of CVH
- ✓ Well-tolerated with no safety signals of potential clinical concern

## Discussion topics

1	Introduction & Overview	Neil Kumar, PhD Chief Executive Officer
2	ATTRIBUTE-CM Phase 3 Topline Results	Jonathan Fox, MD, PhD Chief Medical Officer, Cardiorenal
3	<b>Next Steps</b>	Uma Sinha, PhD Chief Scientific Officer
4	Commercial Launch Plans	Matt Outten, MBA Chief Commercial Officer
5	Q&A Session	



## First regulatory submission planned for year-end 2023



**Present ATTRIBUTE-CM Primary Results**  
European Society of Cardiology 2023  
August 27<sup>th</sup>, 2023



**File New Drug Application (NDA) with FDA**  
End of 2023



**Submit additional regulatory filings (EMA & others)**  
2024



**Execute lifecycle management**  
**Initiate primary prevention study (ACT-EARLY)**  
2024

## Discussion topics

1	Introduction & Overview	Neil Kumar, PhD Chief Executive Officer
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4	<b>Commercial Launch Plans</b>	Matt Outten, MBA Chief Commercial Officer
5	Q&A Session	

## Commercial launch plans

### **We have a world-class commercial team and we are prepared to go to market**

- 20+ FTEs (Pharmacyclics, Vertex, and Schering Plough alumni) and a distinctive commercial advisory board, inclusive of Fred Hassan, Jennifer Cook and Jim Robinson
- Have initiated discussions with key partners (payers and distributors) to bring this drug to patients

### **Our goal is to continue working closely with current and future partners to bring this next generation stabilizer to as broad a patient and provider community as possible**

- Access
- Global reach

**More details on commercial execution to come**

# ATTRibute-CM Phase 3 Topline Results

Q&A Session

