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rigorous science

Featured research in the ATTR-CM landscape

May 29, 2024

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

Acoramidis was designed to achieve maximal stabilization and preserve native TTR

Design Objectives	Rationale
1 **Maximize TTR stabilization/minimize toxic monomer**	• Strong genotype/phenotype correlation between TTR instability and disease severity[1] • Dose-dependent improvements in both TTR stabilization and clinical outcomes demonstrated by tafamidis in ATTR-CM[2] • Extent of TTR stabilization or knockdown associated with degree of clinical benefit in ATTR-PN[3-6]
2 **Preserve circulating native TTR**	• TTR has been highly conserved throughout evolution[7] • 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, potent TTR stabilizer

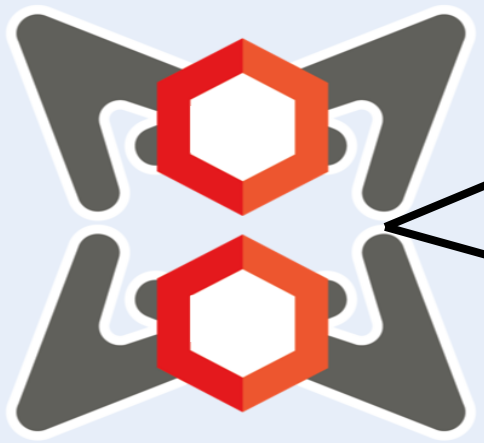
TTR = Transthyretin; ATTR-CM = TTR amyloid cardiomyopathy.

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

Connecting the dots: near-complete TTR stabilization leads to improved clinical outcomes

Genetics → **Stabilization** → **Evidence of Disease (Activation and Treatment Response)** → **Clinical and Functional Outcomes**

Protective T119M mutation

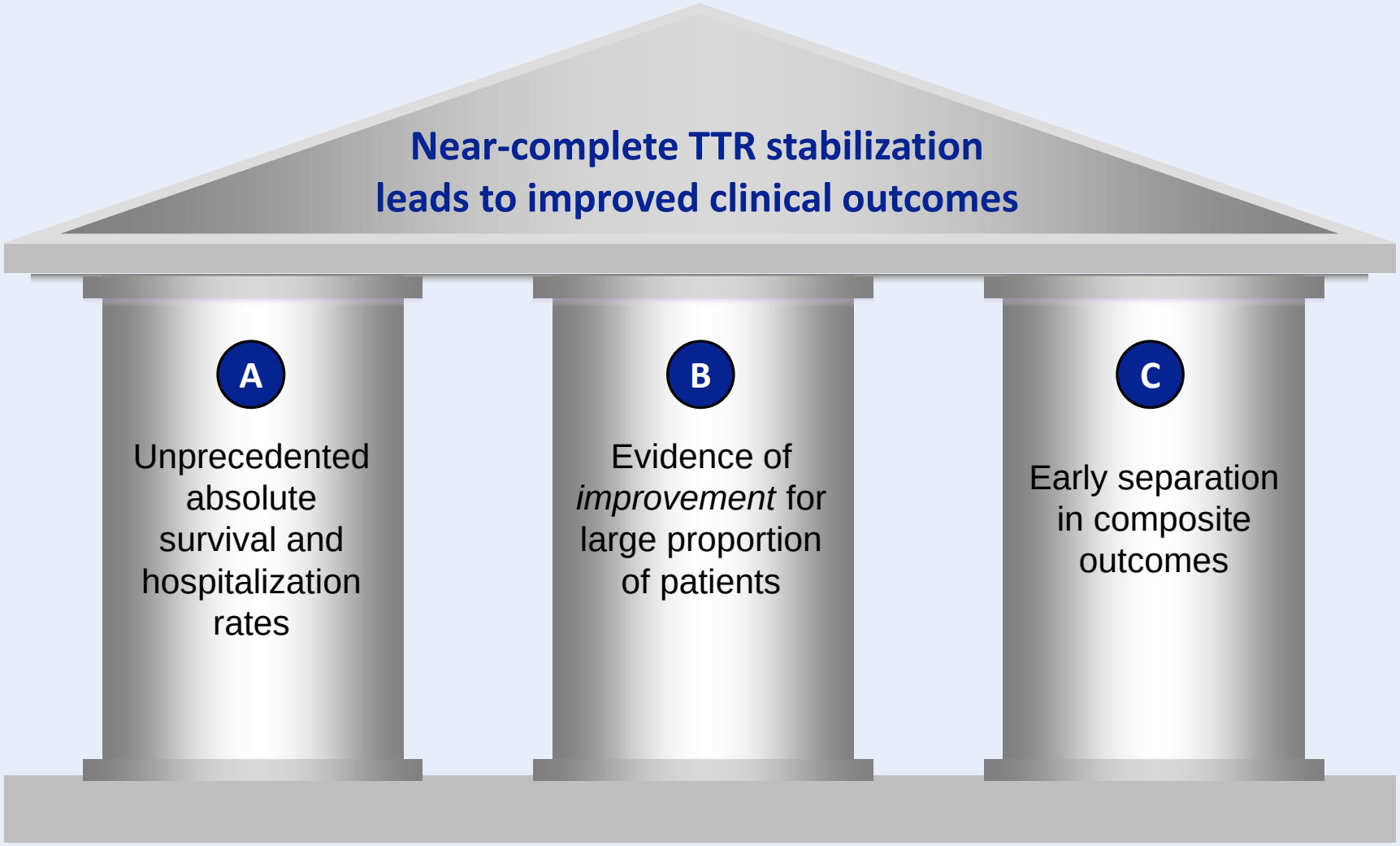


- **Serum TTR**
- **NT-proBNP**

- **ACM[1,2]**
- **CVM[3]**
- **CVH[4]**
- **6MWT**
- **KCCQ**

1. Maurer et al., ISA 2024 “Early Increase in Serum Transthyretin Level is an Independent Predictor of Improved Survival in ATTR Cardiomyopathy: Insights From Acoramidis Phase 3 Study ATTRibute-CM”.
2. Law S, Petrie A, Chacko L, et al. *Heart* 2022;108:474–478.
3. Ambardekar et al., ISA 2024 “Acoramidis Treatment-related Increase in Serum TTR is Associated with Lower Cardiovascular Mortality in ATTR-CM: Insights from ATTRibute-CM”.
4. Cheng et al., ISA 2024 “Acoramidis Treatment-Related Increase in Serum TTR is Associated with a Lower Risk of Cardiovascular Hospitalization in ATTR-CM Patients: Insights from the ATTRibute-CM Trial”.

Patients on acoramidis are surviving more and going to the hospital less



Patients on acoramidis are surviving more and going to the hospital less

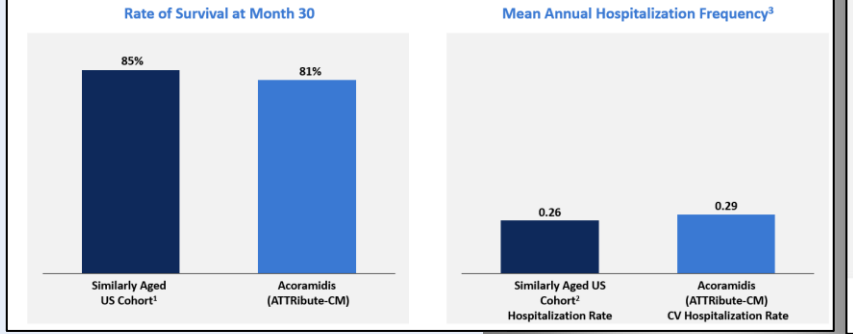
Near-complete TTR stabilization leads to improved clinical outcomes

A

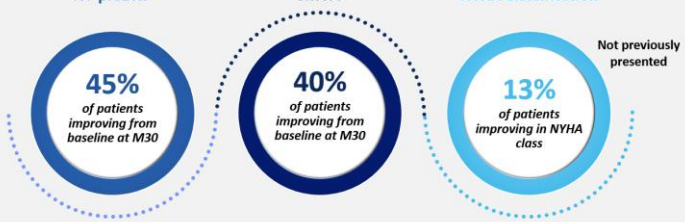
B

C

A Observed effect of acoramidis approaches rates of mortality and hospitalization in similarly aged US cohorts



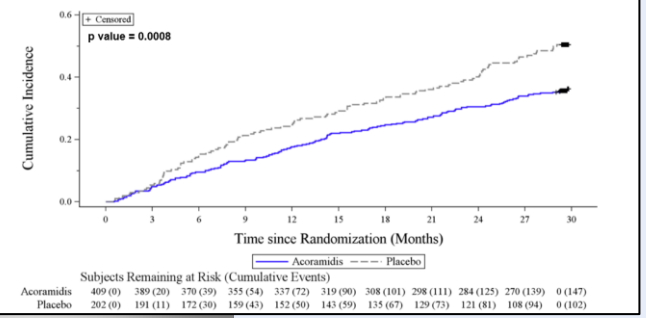
B >40% of mITT participants with data at Month 30 experienced improvement in laboratory and functional measures of disease progression on acoramidis



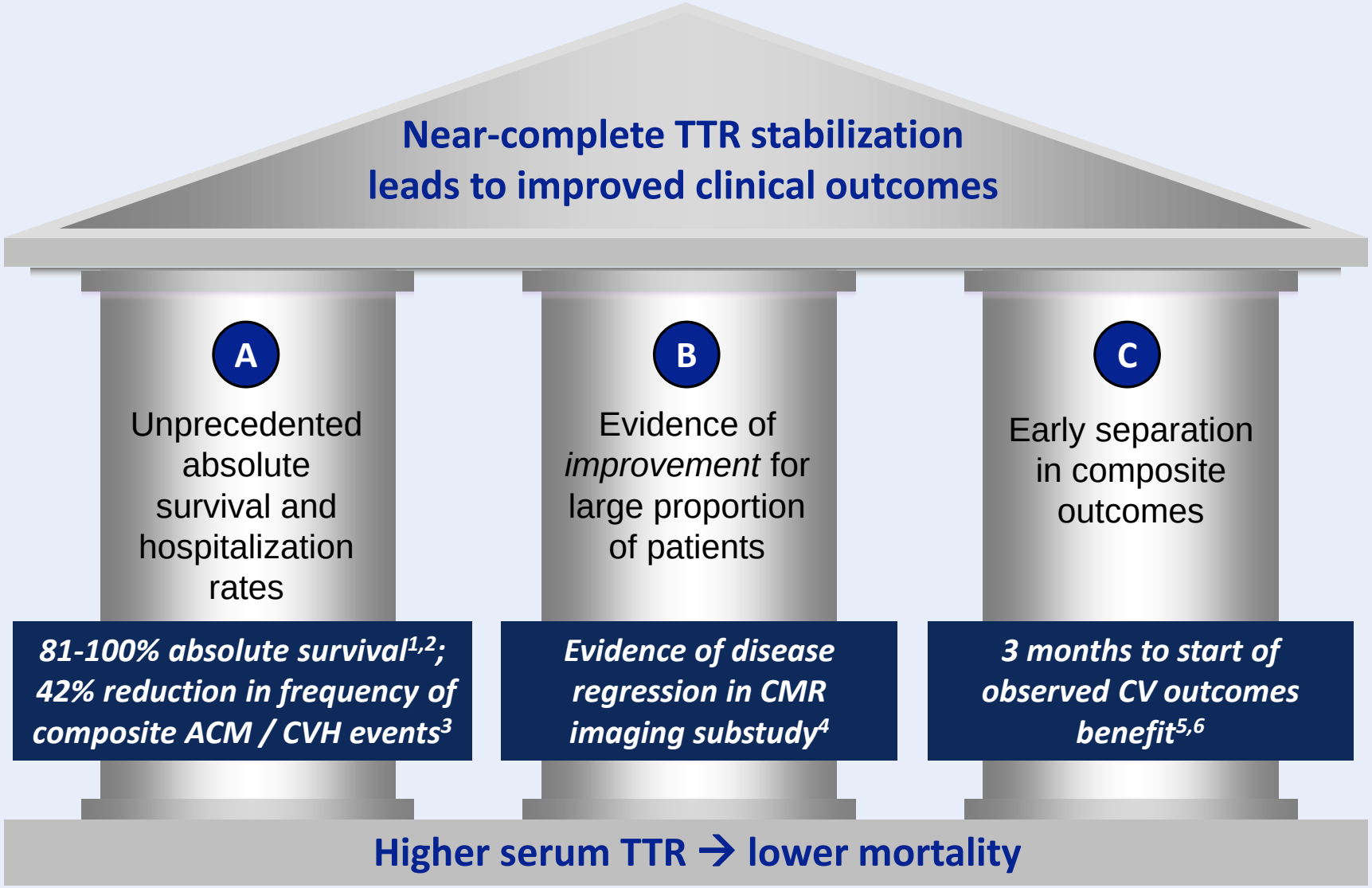
The proportion of patients improving on acoramidis across laboratory and functional measures represent the best observed improvements from prior interventional studies or benchmarks, to the company's knowledge. Even using a conservative imputation method that attributes missing values as unfavorable, the improvements are still the highest observed to the company's knowledge.

C Time to ACM or First CVH separated in favor of acoramidis by Month 3

Time to All-Cause Mortality or First Cardiovascular-Related Hospitalization Over 30 Months



Patients on acoramidis are surviving more and going to the hospital less



1. Gilmore J, et al. Efficacy and Safety of Acoramidis in Transthyretin Amyloid Cardiomyopathy. N Engl J Med 2024; 390:132-142. 2. BridgeBio data on file (Acoramidis Ph3 Japan; NCT04622046). 3. ATTRibute-CM event frequency of ACM and CVH. 4. Razvi et al. Acoramidis may improve cardiac function and promote regression in transthyretin amyloid cardiomyopathy: data from the ATTRibute-CM cardiac magnetic resonance (cmr) substudy; presented at Am Coll Cardiol. 2024. 5. American Heart Association Presentation, BridgeBio - Acoramidis Improves Clinical Outcomes in ATTR-CM: Additional Data from ATTRibute-CM Phase 3 Study; presented Nov 12, 2023. 6. Alexander et al., ISA 2024 "Acoramidis Achieves Early Reduction in Cardiovascular Death or Hospitalization in Transthyretin Amyloid Cardiomyopathy (ATTR-CM): Results from the ATTRibute-CM Clinical Trial".

Acoramidis continues to expand upon its clinically differentiated safety and efficacy profile

Category	Title	First Author[1]	Congress
Clinical Outcomes *8 total*	Early Increase in Serum Transthyretin Level is an Independent Predictor of Improved Survival in ATTR Cardiomyopathy: Insights from Acoramidis Phase 3 Study ATTRibute-CM	Maurer, M.	ISA ‘24
	Acoramidis Treatment-related Increase in Serum TTR is Associated with Lower Cardiovascular Mortality in ATTR-CM: Insights from ATTRibute-CM	Ambardekar, A.	ISA ‘24
	Acoramidis Treatment-Related Increase in Serum TTR is Associated with a Lower Risk of Cardiovascular Hospitalization in ATTR-CM Patients: Insights from the ATTRibute-CM Trial	Cheng, R.	ISA ‘24
	Acoramidis Achieves Early Reduction in Cardiovascular Death or Hospitalization in Transthyretin Amyloid Cardiomyopathy (ATTR-CM): Results from the ATTRibute-CM Clinical Trial	Alexander, K.	ISA ‘24
	Higher Risk of Mortality in Previously Hospitalized Patients: Insights from ATTRibute-CM	Masri, A.	ISA ‘24
	Acoramidis Improves Clinical Outcomes in Transthyretin Amyloid Cardiomyopathy	Judge, D.	AHA ‘23 (Encore: ISA ’24)
	ATTRibute-CM: ITT Sensitivity Analysis and Sub-Analysis Comparing Acoramidis and Placebo in Stage 4 CKD	Poulsen, S.	ESC-HF ’24 (Encore: ISA ’24)
	BridgeBio Pharma Shares Positive Results of Single-Arm Phase 3 Study of Acoramidis in Japanese Patients with Transthyretin Amyloid Cardiomyopathy (ATTR-CM) Including No Mortality Reported in the Trial at 30 Months	--	Press Release
Quality of Life *2 total*	Health-Related Quality of Life in Patients with Symptomatic Transthyretin Amyloid Cardiomyopathy Treated with Acoramidis: An EQ-5D Analysis from the ATTRibute-CM Study	Hanna, M.	ESC-HF ’24 (Encore: ISA ’24)
	Improved Health-Related Quality of Life in Acoramidis-Treated Patients with ATTR-CM, Demonstrated by Improvements in KCCQ Scores	Fontana, M.	ESC-HF ’24 (Encore: ISA ’24)
Biomarkers	Acoramidis significantly improves NT-proBNP indices that indicate ATTR-CM disease progression and predict subsequent mortality: Insights from the ATTRibute-CM Study	Garcia-Pavia, P.	ESC-HF ’24 (Encore: ISA ’24)
Imaging	Acoramidis May Improve Cardiac Function And Promote Regression In ATTR-CM: Data From The ATTRibute-CM Cardiac Magnetic Resonance (CMR) Substudy	Razvi, Y.	ACC ’24 (Encore: ISA ’24)
Prevention	Rationale & Design of ACT-EARLY, the Acoramidis Transthyretin Amyloidosis Prevention Trial	Garcia-Pavia, P.	ISA ‘24

[1]Presenters may differ from first author due to presenter availability.

New updates at ISA: Focus of today's call

- **Greater stabilization leads to better clinical outcomes**
  - For every 5 mg/dL increase in serum TTR level, the risk of death was reduced by 30.9% by the logistic model and by 26.1% by the Cox proportional hazards model[1]

- **CVH is predictive of overall survival in ATTR-CM over 30 months, with acoramidis demonstrating the earliest time to separation (3 months) on composite clinical outcomes**[2,3]
  - Acoramidis demonstrated unprecedented survival in both those with (62%) or without (87%) previous hospitalization[4]

1. Maurer et al., ISA 2024 "Early Increase in Serum Transthyretin Level is an Independent Predictor of Improved Survival in ATTR Cardiomyopathy: Insights From Acoramidis Phase 3 Study ATTRibute-CM
2. American Heart Association Presentation, BridgeBio - Acoramidis Improves Clinical Outcomes in ATTR-CM: Additional Data from ATTRibute-CM Phase 3 Study; presented Nov 12, 2023.
3. Alexander et. al., ISA 2024 "Acoramidis Achieves Early Reduction in Cardiovascular Death or Hospitalization in Transthyretin Amyloid Cardiomyopathy (ATTR-CM): Results from the ATTRibute-CM Clinical Trial
4. Masri et al., ISA 2024 "Higher Risk of Mortality in Previously Hospitalized Patients: Insights from ATTRibute-CM"; ATTRibute-CM, Data on file

Early Increase in Serum Transthyretin Level is an Independent Predictor of Improved Survival in ATTR-CM: Insights From Acoramidis Phase 3 Study ATTRibute-CM

Mathew S. Maurer, Nitasha Sarswat, Martha Grogan, Amrut Ambardekar, Anique Ducharme, Steen Hvitfeldt Poulsen, Satish Rao, Jean-François Tamby, Jonathan C. Fox, Brian Adam, Surendhar Reddy Chepyala, Bill Poland, and Uma Sinha

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Objective

To report the results of acoramidis-mediated change in serum TTR, an in vivo measure of TTR stabilization, and its relationship to All-Cause Mortality (ACM) in ATTRibute-CM

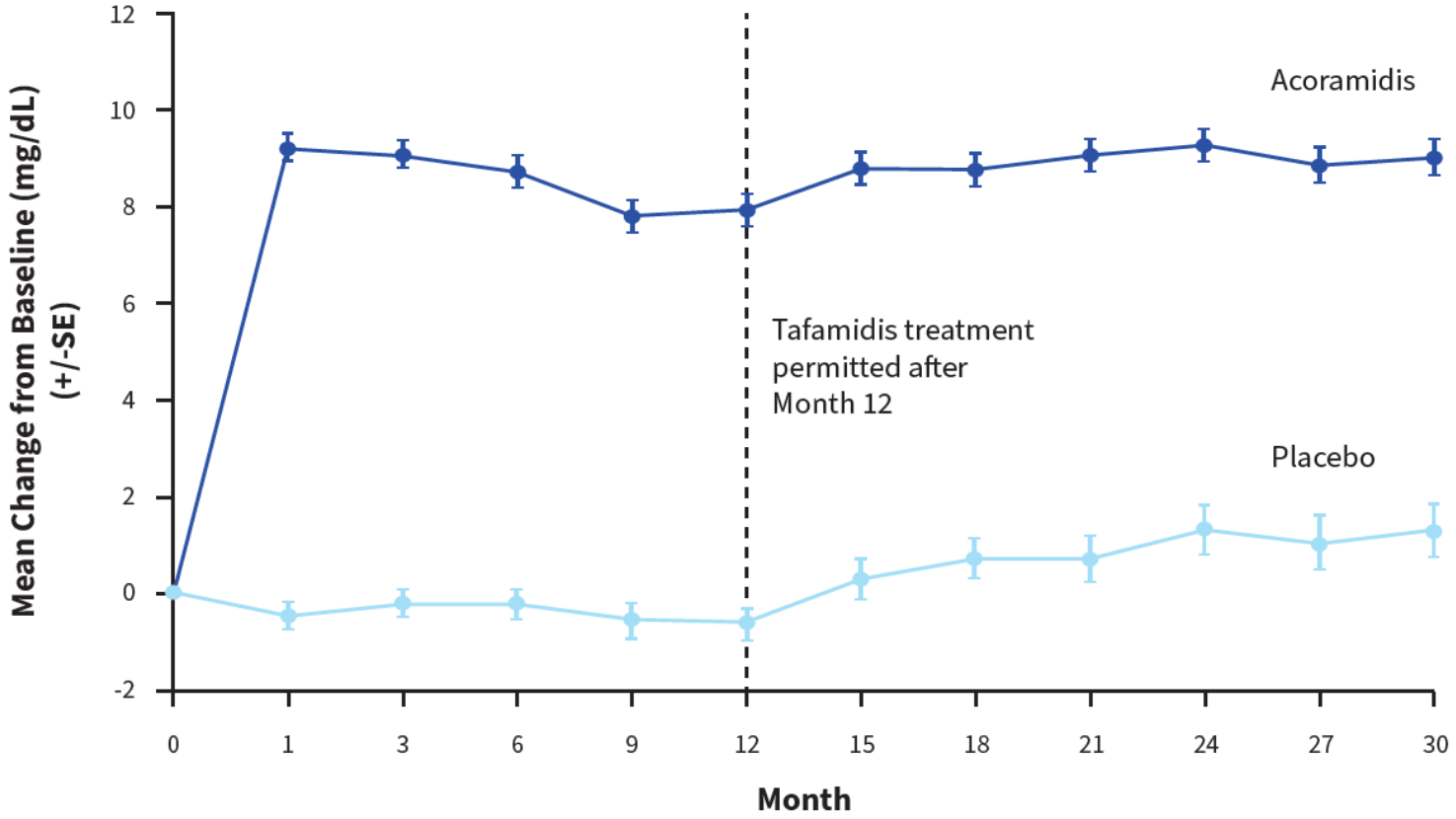
Methodology

- Utilizing ATTRibute-CM data, modeling and simulation analyses were performed to describe the population pharmacokinetics of acoramidis and evaluate the safety and efficacy exposure-response relationships for acoramidis (n=558)
- Exposure-response relationships were modeled for ACM vs serum TTR
- Change from baseline in serum TTR shows observed measurements without any imputation

Source: Maurer et al., ISA 2024 “Early Increase in Serum Transthyretin Level is an Independent Predictor of Improved Survival in ATTR Cardiomyopathy: Insights From Acoramidis Phase 3 Study ATTRibute-CM”

Patients on acoramidis observed a rapid and sustained increase in serum TTR over 30 months

FIGURE 1: Change From Baseline in Serum TTR Levels—mITT Population



Observed measurements without any imputation. No adjustment was made for early discontinuation for any reason, including death.

Acoramidis treatment increased serum TTR levels at Day 28, which remained stable through Month 30

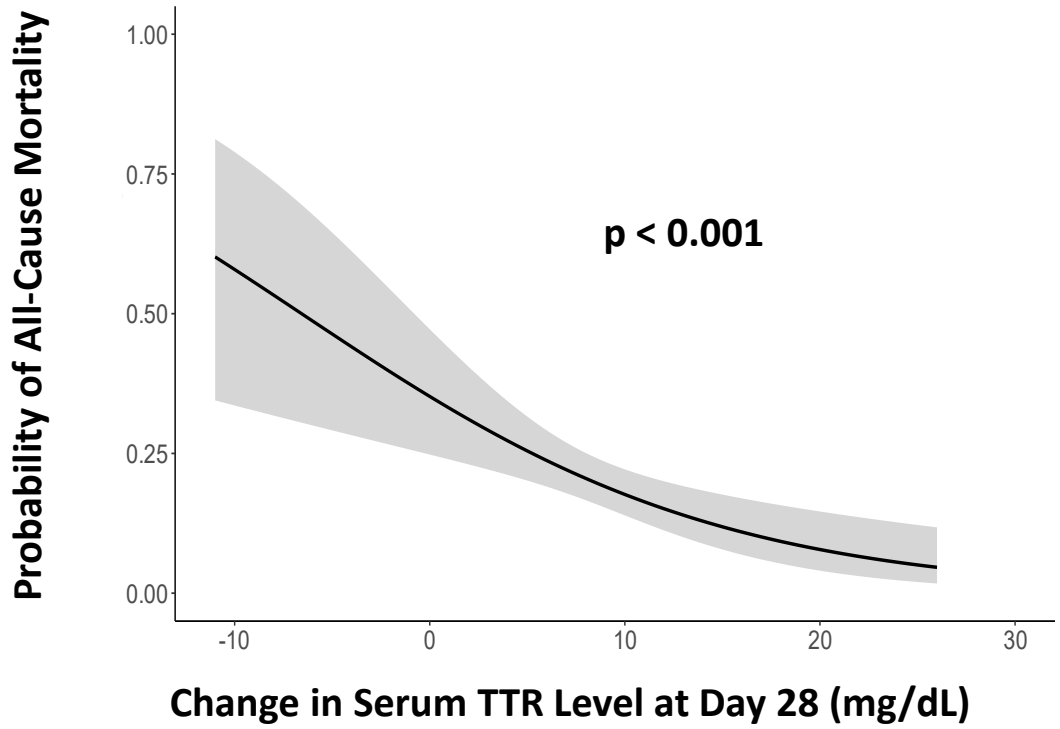
Source: Maurer et al., ISA 2024 "Early Increase in Serum Transthyretin Level is an Independent Predictor of Improved Survival in ATTR Cardiomyopathy: Insights From Acoramidis Phase 3 Study ATTRibute-CM"

Stat-sig correlation of increasing serum TTR levels and decreasing risk of death was observed in ATTR-CM patients on acoramidis

For every 5 mg/dL increase in serum TTR level, the risk of death was reduced by 30.9% by the logistic model and by 26.1% by the Cox proportional hazards model.*

NOTE: In a multi-variate analysis, changes in serum TTR remained an independent predictor of all cause mortality even after adjusting for all other variables

FIGURE 2: Probability of All-Cause Mortality as a Function of Change from Baseline Serum TTR Level at Day 28 in Acoramidis Treated Cohort



ATTR-CM = transthyretin cardiac amyloidosis, TTR = transthyretin

*Data based on mITT population adjusting for baseline demographic variables, use of diuretics, New York Heart Association class, baseline serum TTR, TTR variant vs wild type and National Amyloidosis Centre stage

Source: Maurer et al., ISA 2024 "Early Increase in Serum Transthyretin Level is an Independent Predictor of Improved Survival in ATTR Cardiomyopathy: Insights From Acoramidis Phase 3 Study ATTRibute-CM"

Real-World Outcomes of Tafamidis in Transthyretin Cardiomyopathy

Ahmad Masri, Priyanka Bhattacharya, Brent Medoff, Ain U. Ejaz, Pranav Chandrashekar, Lauren Ives, Alfonsina Mirabal Santos, Sergio L. Teruya, Yuanzi Zhao, Shuaiqi Huang, Xiaofeng Wang, Brett W. Sperry, Mathew S. Maurer, Prem Soman, Mazen Hanna

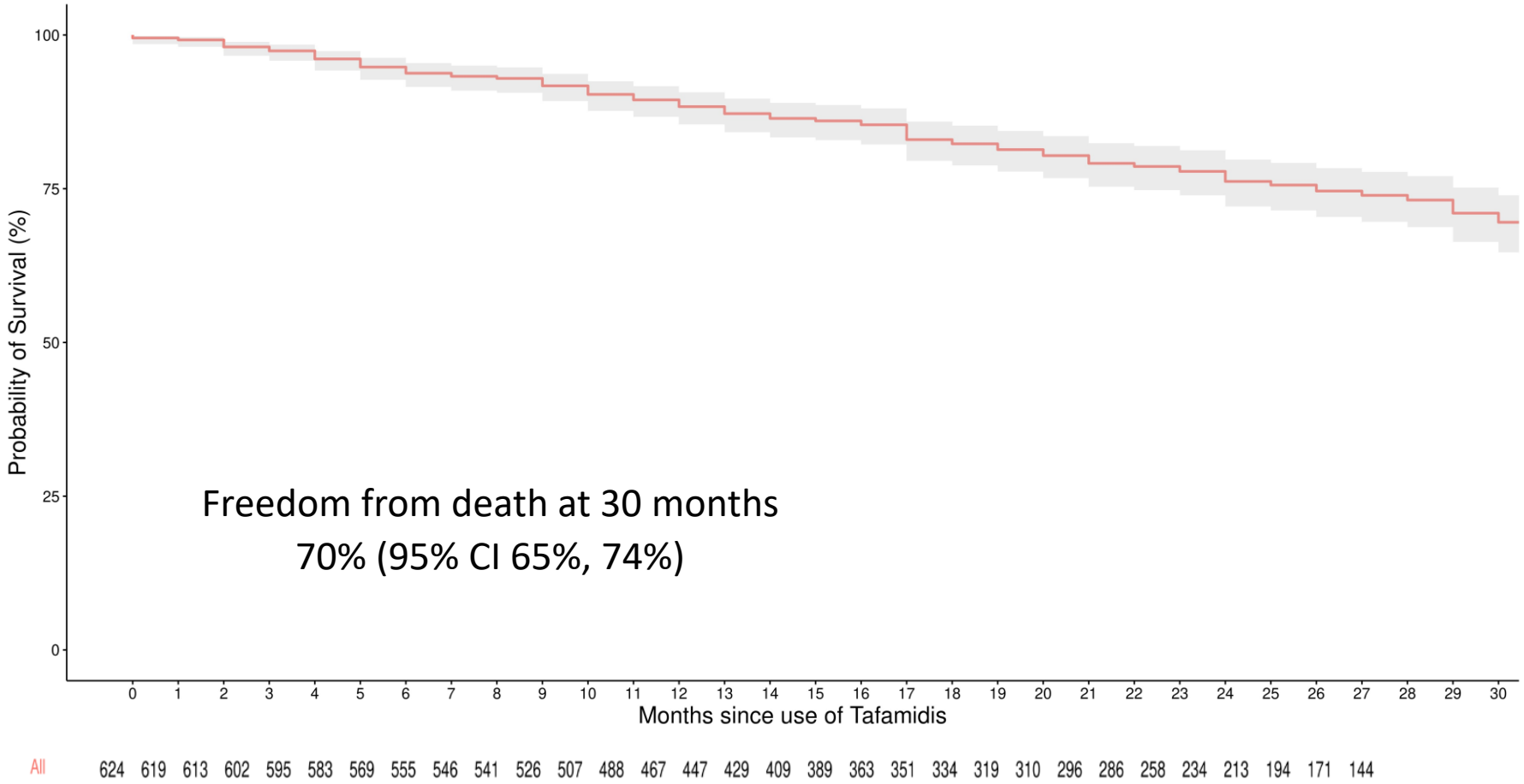
Methods

- Patients with ATTR-CM who received tafamidis between 1/1/2018 and 10/15/2021 at 5 amyloidosis centers in the US
  - Cleveland Clinic Foundation, University of Pittsburgh Medical Center, Oregon Health & Science University, Columbia University, and University of Missouri - Kansas City
- Primary outcome was all-cause mortality
- Secondary outcome was CV Hospitalization

Baseline Characteristics

Variable	Total (N=624)	wtATTR (N=515)	vATTR (N=109)	p value
Age				<0.0001
Median (Q1, Q3)	78.0 (72.0, 83.0)	79.0 (73.1, 84.0)	71.0 (65.0, 76.0)	
Male sex (%)	546 (87.5%)	469 (91.1%)	77 (70.6%)	
Race (%)				<0.0001
White	507 (81.3%)	472 (91.7%)	35 (32.1%)	<0.0001
Black	109 (17.5%)	38 (7.4%)	71 (65.1%)	
Other	8 (1.3%)	5 (1.0%)	3 (2.8%)	
TTR variant		-		
V122I	77 (12.3%)		77 (70.6%)	
T60A	15 (2.4%)		15 (13.8%)	
V30M	5 (0.8%)		5 (4.6%)	
Other	12 (2.0%)		12 (11.0%)	
NYHA Class (%)				
I	84 (13.5%)	65 (12.6%)	19 (17.4%)	0.1491
II	324 (51.9%)	276 (53.6%)	48 (44.0%)	
III	210 (33.7%)	168 (32.6%)	42 (38.5%)	
IV	6 (1.0%)	6 (1.2%)	0 (0.0%)	
Diagnosis Method (%)				
Endomyocardial biopsy	92 (14.7%)	82 (15.9%)	10 (9.2%)	0.0900
Bone Scintigraphy	498 (79.8%)	408 (79.2%)	90 (82.6%)	
Others	34 (5.4%)	25 (4.9%)	9 (8.3%)	
ATTR-CM diagnosis to tafamidis start (months)*	12.1 (16.3)	11.5 (15.4)	14.9 (19.7)	

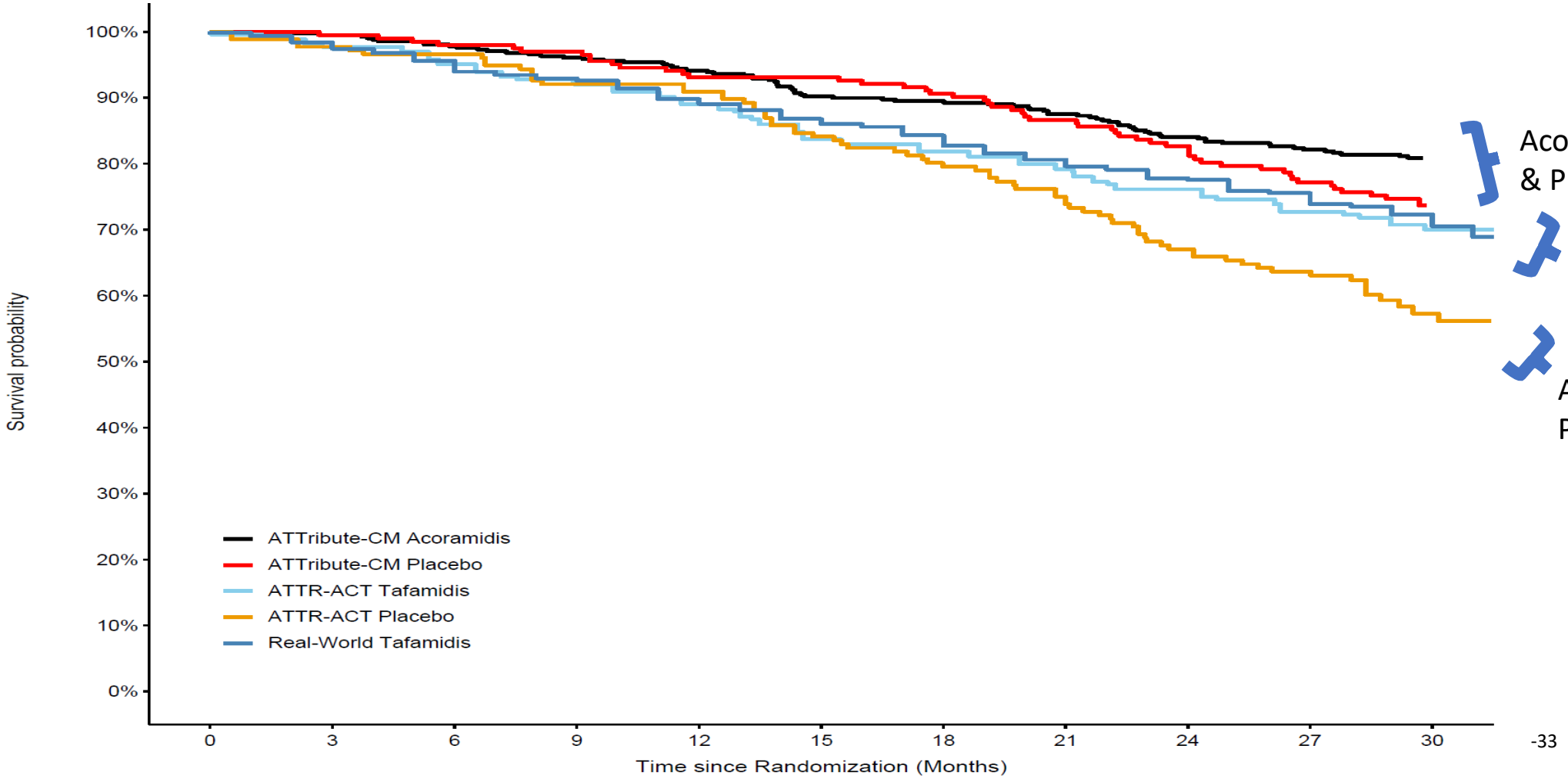
Primary Outcome: All-Cause Mortality



Median Follow-up (years) : 1.8 (1.1, 2.5)

142 (23%) Died

Tafamidis' survival rates in the contemporary ATTR-CM population were comparable to ATTR-ACT



Acoramidis & Placebo

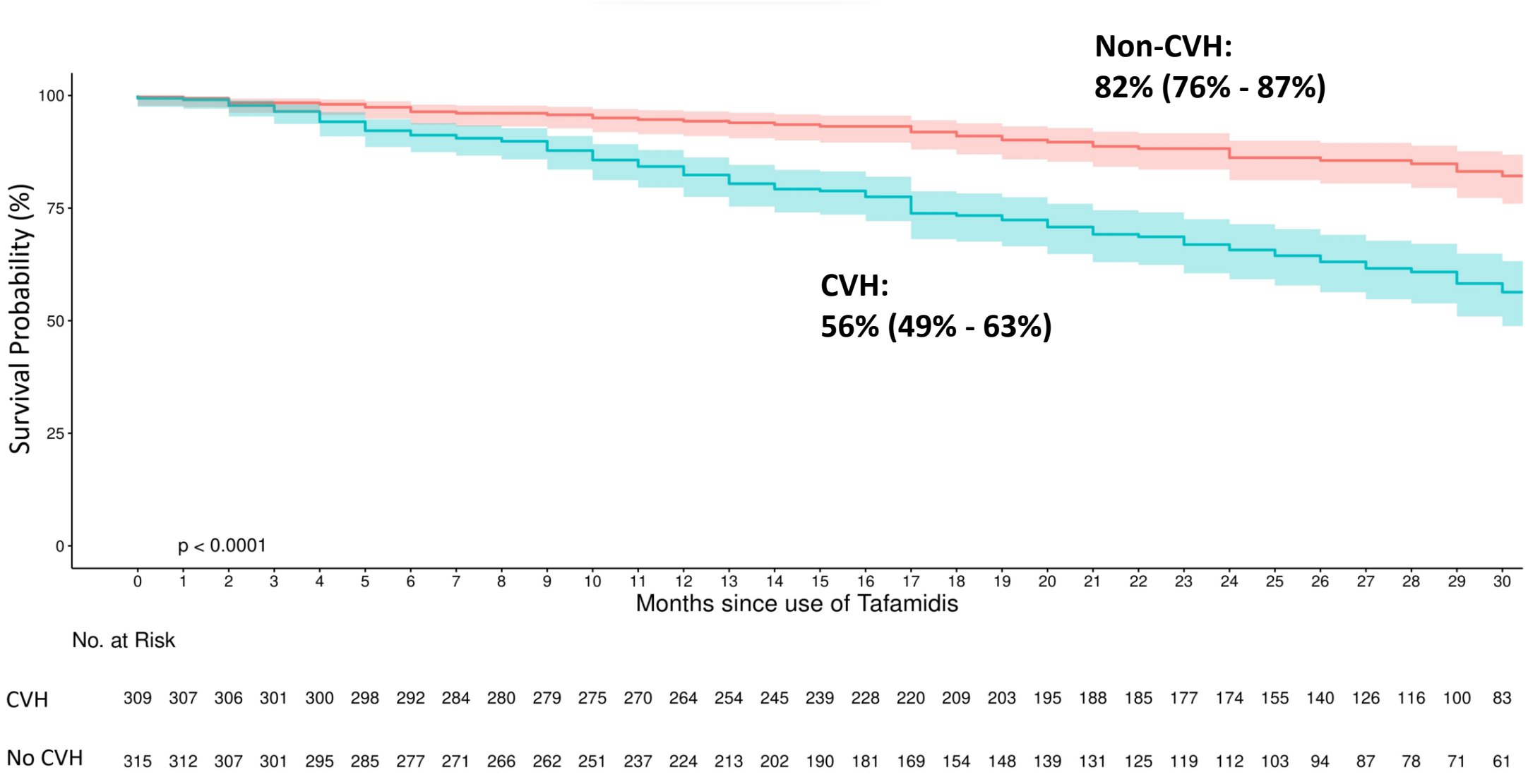
Tafamidis (ATTR-ACT & RWE)

ATTR-ACT Placebo

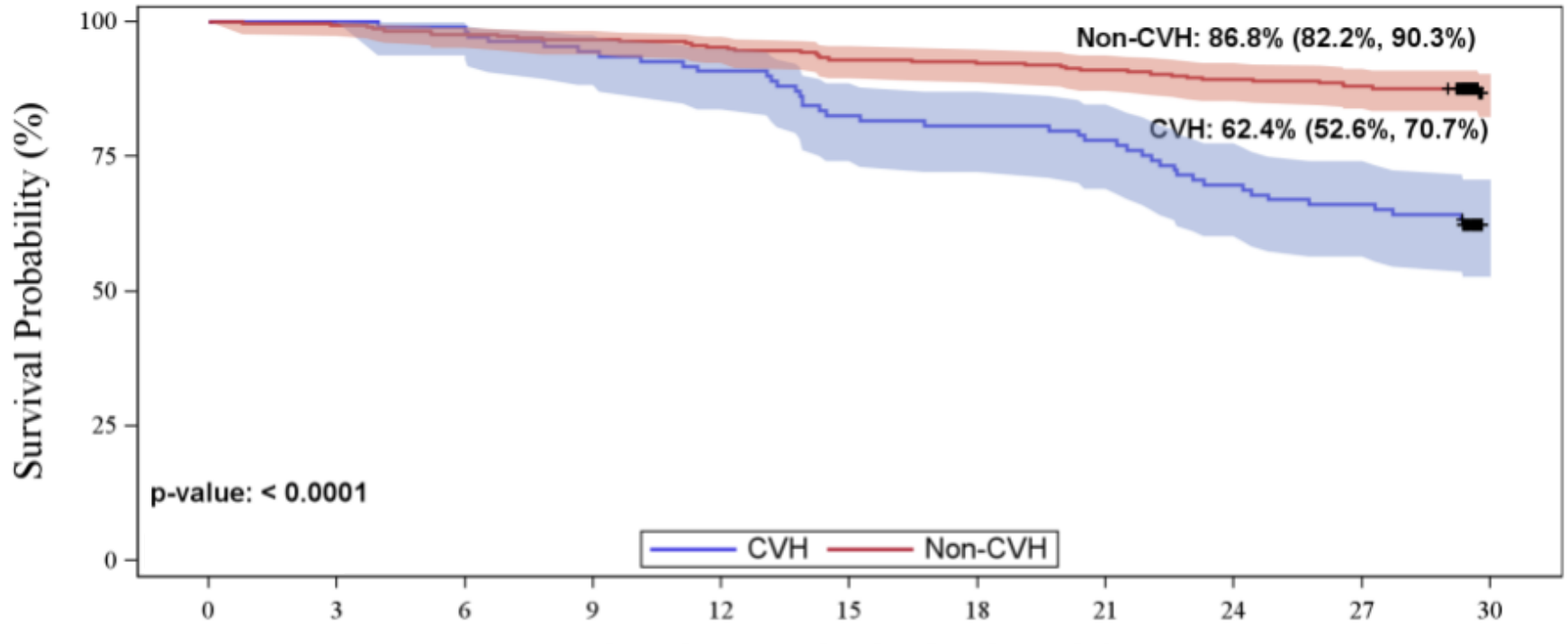
Number at risk (number of events)

ATTribute-CM Acoramidis	409 (0)	407 (2)	401 (8)	393 (16)	385 (24)	369 (40)	365 (44)	358 (51)	344 (65)	336 (73)	0 (79)
ATTribute-CM Placebo	202 (0)	201 (1)	198 (4)	196 (6)	188 (14)	188 (14)	183 (19)	175 (27)	166 (36)	156 (46)	0 (52)
ATTR-ACT Tafamidis	264 (0)	259 (5)	252 (12)	244 (20)	235 (29)	222 (42)	216 (48)	209 (55)	200 (64)	193 (71)	99 (78)
ATTR-ACT Placebo	177 (0)	173 (4)	171 (6)	163 (14)	161 (16)	150 (27)	141 (36)	131 (46)	118 (59)	113 (64)	51 (75)
Real-World Tafamidis	624 (1)	607 (16)	576 (37)	544 (45)	493 (65)	439 (81)	372 (96)	323 (109)	288 (117)	226 (129)	160 (137)

Survival based on previous CV hospitalizations (Tafamidis)



Survival based on previous CV hospitalizations (Acoramidis)



Subjects Remaining at Risk (Cumulative Events)

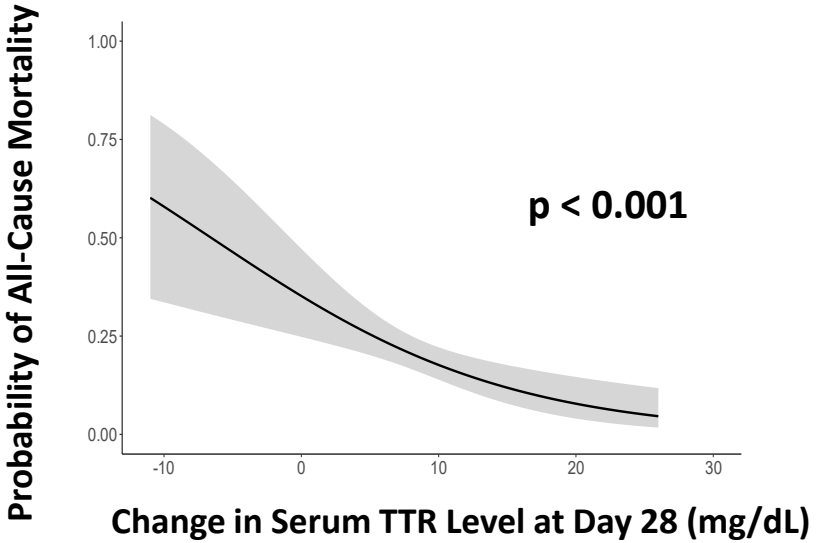
CVH	109 (0)	109 (0)	108 (1)	103 (6)	99 (10)	90 (19)	88 (21)	85 (24)	76 (33)	72 (37)	0 (41)
Non-CVH	300 (0)	298 (2)	293 (7)	290 (10)	286 (14)	279 (21)	277 (23)	273 (27)	268 (32)	264 (36)	0 (38)

Source: ATTRibute-CM, Data on file.
Note: "+" symbol used to represent when a patient is censored at a given time. Cardiovascular-related hospitalization includes both CEC adjudicated CV-related hospitalization and Events of clinical interest (EOCI). CVH group includes subjects with any CVH event. Non-CVH group includes subjects without any CVH event. p-value was calculated using Log-Rank Test to compare the survival distribution of CVH group vs. Non-CVH group for Acoramidis Subjects

Tying it all together: Near-complete TTR stabilization leads to improved clinical outcomes

- Patients on acoramidis observed unprecedented 81-100% absolute survival at month 30[1,2]
- Patients with at least one CVH have a significantly higher risk of mortality, highlighting the need for ATTR-CM treatments that reduce CVH[3]
  - Acoramidis demonstrated 42% reduction in frequency of composite ACM / CVH events in ATTRibute-CM[4]
  - Acoramidis demonstrates the earliest time to separation (3 months) on composite clinical outcomes[5]
- Acoramidis meaningfully improved quality of life as assessed by both KCCQ and EQ-5D analysis[7,8]

Increased serum TTR levels → decreased risk of death[6]



Looking Forward: PDUFA date 11/29

1. Gilmore J, et al. Efficacy and Safety of Acoramidis in Transthyretin Amyloid Cardiomyopathy. N Engl J Med 2024; 390:132-142. 2. BridgeBio data on file (Acoramidis Ph3 Japan; NCT04622046). 3. ATTRibute-CM, Data on file.
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6. Maurer et al., ISA 2024 "Early Increase in Serum Transthyretin Level is an Independent Predictor of Improved Survival in ATTR Cardiomyopathy: Insights From Acoramidis Phase 3 Study ATTRibute-CM".
7. Hanna et al., ESC HF 2024 "Health-Related Quality of Life in Patients with Symptomatic Transthyretin Amyloid Cardiomyopathy Treated with Acoramidis: An EQ-5D Analysis from the ATTRibute-CM Study".
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