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): **March 21, 2023**

CVRx, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-40545**	**41-1983744**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

9201 West Broadway Avenue, Suite 650
Minneapolis, MN 55445
(Address of principal executive offices) (Zip Code)

(763) 416-2840
(Registrant's telephone number, including area code)

N/A
(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 (see General Instruction A.2. below):

☐ 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 $0.01 per share	**CVRX**	**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.

As announced earlier by CVRx, Inc. (the "Company"), the previously-released preliminary results of the Company's BeAT-HF post-market randomized clinical trial will be discussed at the second annual Technology and Heart Failure Therapeutics (THT) conference on March 21, 2023. The results will be presented by Dr. Michael Zile, followed by a symposium sponsored by the Company. The Company will also host an investor conference call at 4:30 pm Eastern Time on March 21, 2023 to discuss the results.

A press release summarizing the detailed results and the presentation materials, which will also be used for the investor conference, are attached as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information contained in this Item 7.01, including Exhibits 99.1 and 99.2, is being furnished and shall not be deemed to be "filed" with the Securities and Exchange Commission 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 and is not incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On March 21, 2023, the Company issued a press release announcing highlights of the data from the BeAT-HF post-market randomized clinical trial, as follows:

- **Safety - Major Adverse Neurological or Cardiovascular (MANCE) system or procedure-related event-free rate**
  - MANCE-free rate of 97% ($p<0.001$)
- **Long-term symptom improvement for Barostim Baroreflex Activation Therapy (BAT) vs. Control:**
  - 6 Minute Hall Walk improved by 44 meters at 12 months (nominal $p<0.001$)
  - Quality of Life improved by 10 points in Minnesota Living with Heart Failure Questionnaire at 24 months (nominal $p<0.001$)
  - NYHA Class improved in 27% more BAT patients at 24 months (nominal $p<0.001$)
- **Mortality (cardiovascular death, LVAD, heart transplant) and morbidity (HF hospitalizations, ER visits) – primary endpoint**
  - No statistically significant difference [Rate Ratio 0.94, (95% Confidence Interval 0.57, 1.57); $p=0.82$]
- **All-cause mortality (all-cause death, LVAD, heart transplant)**
  - 34% relative reduction in BAT vs. Control [Hazard Ratio 0.66 (95% CI 0.44, 1.007); nominal $p=0.054$]
- **Hierarchical composite of cardiovascular death, LVAD, heart transplant, HF hospitalization, and Quality of Life using Win Ratio**
  - Win Ratio of 1.26 favored BAT vs. Control [95% CI 1.02, 1.58; nominal $p=0.04$]

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release of CVRx, Inc., dated March 21, 2023
99.2	Presentation of CVRx, Inc., dated March 21, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

CVRx, Inc.

Date: March 21, 2023

By: /s/ Jared Oasheim
Name: Jared Oasheim
Its: Chief Financial Officer

Exhibit 99.1

Totality of Evidence from BeAT-HF Study Shows CVRx's Barostim Provides Long-term Benefits for Patients with Heart Failure

MINNEAPOLIS, Mar. 21, 2023 – CVRx, Inc. (NASDAQ: CVRX) ("CVRx"), a commercial-stage medical device company focused on developing, manufacturing and commercializing Barostim™, an innovative extravascular implantable neuromodulation device for patients with cardiovascular diseases, announced detailed preliminary results of the post-market phase of the BeAT-HF trial at the second annual Technology and Heart Failure (HF) Therapeutics (THT) conference on Tuesday, March 21, 2023. These results are being presented by Dr. Michael Zile, Professor of Cardiology at the Medical University of South Carolina (MUSC).

Highlights of the data presented by Dr. Zile include:

- **Safety - Major Adverse Neurological or Cardiovascular (MANCE) system or procedure-related event-free rate**
  - MANCE-free rate of 97% ($p<0.001$)
- **Long-term symptom improvement for Barostim Baroreflex Activation Therapy (BAT) vs. Control:**
  - 6 Minute Hall Walk improved by 44 meters at 12 months (nominal $p<0.001$)
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  - Win Ratio of 1.26 favored BAT vs. Control [95% CI 1.02, 1.58; nominal $p=0.04$]

Dr. Zile's presentation concludes that the "Totality of evidence indicates that BAT is a safe, effective and durable treatment for patients with heart failure with reduced ejection fraction." The slides from Dr. Zile's featured presentation, as well as key slides that will be presented as part of the CVRx-sponsored THT symposium, can be found at ir.cvrx.com.

"We are happy to see the significant long-term data that favored Barostim," added Nadim Yared, President and CEO of CVRx. "Interest and adoption of the therapy continue to expand based on the previously-approved claims, and now we look forward to submitting this new data to the FDA to pursue expanded labeling for Barostim. We are forever grateful to the patients, investigators, nurses, and research staff involved in the study."

The full results of BeAT-HF, including a number of additional analyses and endpoints, will be submitted by the executive steering committee for publication in one or more peer-reviewed journals. CVRx anticipates that regulatory submission to the FDA for expanded labeling will be made in the coming months.

About CVRx, Inc.

CVRx is a commercial-stage medical device company focused on the developing, manufacturing and commercializing innovative neuromodulation solutions for patients with cardiovascular diseases. Barostim™ is the first medical technology approved by FDA that uses neuromodulation to improve the symptoms of patients with heart failure. Barostim is an implantable device that delivers electrical pulses to baroreceptors located in the wall of the carotid artery. Baroreceptors activate the body's baroreflex, which in turn triggers an autonomic response to the heart. The therapy is designed to restore balance to the autonomic nervous system and thereby reduce the symptoms of heart failure. Barostim received the FDA Breakthrough Device designation and is FDA-approved for use in heart failure patients in the U.S. It has also received the CE Mark for heart failure and resistant hypertension in the European Economic Area. To learn more about Barostim, visit www.cvrx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements, including statements regarding our future financial performance, our anticipated growth strategies, anticipated trends in our industry, our business prospects and our opportunities, including specifically those related to potential new indications, labelling or marketing opportunities, our continued review and analysis of trial data and future business and financial impacts. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "outlook," "guidance," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

The forward-looking statements in this press release are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions, including, uncertainties related to obtaining regulatory approvals, further analysis and understanding of clinical trial data, physician and patient adoption, and other important factors that could cause actual results, performance or achievements to differ materially from those projected in the forward-looking statements that are found in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, as such factors may be updated from time to time in our other filings with the Securities and Exchange Commission. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Media Contact:
Laura O'Neill
Finn Partners
212-867-1762
laura.oneill@finnpartners.com

Investor Contact:
Mark Klausner or Mike Vallie
ICR Westwicke
443.213.0501
ir@cvrx.com

Preliminary Results of the Post-Market Phase of the BeAT-HF Randomized Clinical Trial

March 21, 2023

CVR
Outsmart the h

Forward-looking statements

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Baroreflex Activation Therapy (BAT) in Patients with Hear Failure and a Reduced Ejection Fraction (BeAT-HF) Trial: Long – Term Outcomes

BeAT-HF Executive Steering Committee:
Michael R. Zile
JoAnn Lindenfeld
Fred A. Weaver
Faiez Zannad
William T. Abraham

Study Sponsor: CVRx

CRF THT

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Grant/Research Support	NHLBI, VA, DOD
Consulting Fees/Honoraria	Abbott, Boston Scientific, **CVRx**, Corvia, Edwards, EBR, Lilly, Medtronic, Merck, Novartis, Vectorious, V Wave
Major Stock Shareholder/Equity	None
Royalty Income	None
Ownership/Founder	None
Intellectual Property Rights	None
Other Financial Benefit	None

Faculty disclosure information can be found on the app

CRF THT

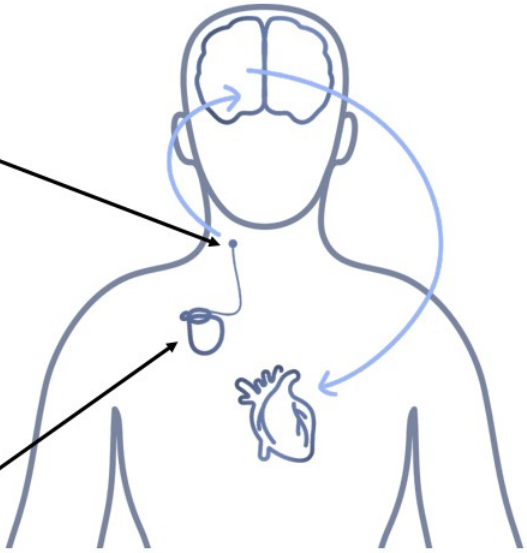
Baroreflex Activation Therapy (BAT) Device (Barostim)

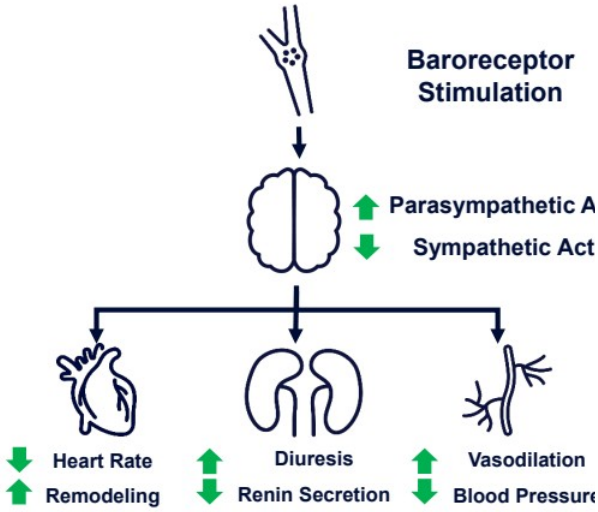
Carotid Sinus Lead

- Extravascular
- 2 mm electrode
- Unipolar design

IPG

- 5 year longevity
- Personalized therapy
- Average programming at 6 Mo:
  - 8.4 mA amplitude
  - 107 ms duration
  - 43 pps frequency





BeAT-HF Trial Design

Prospective, multicenter, randomized, 2-arm, parallel-group, open-label with blinded evaluation trial

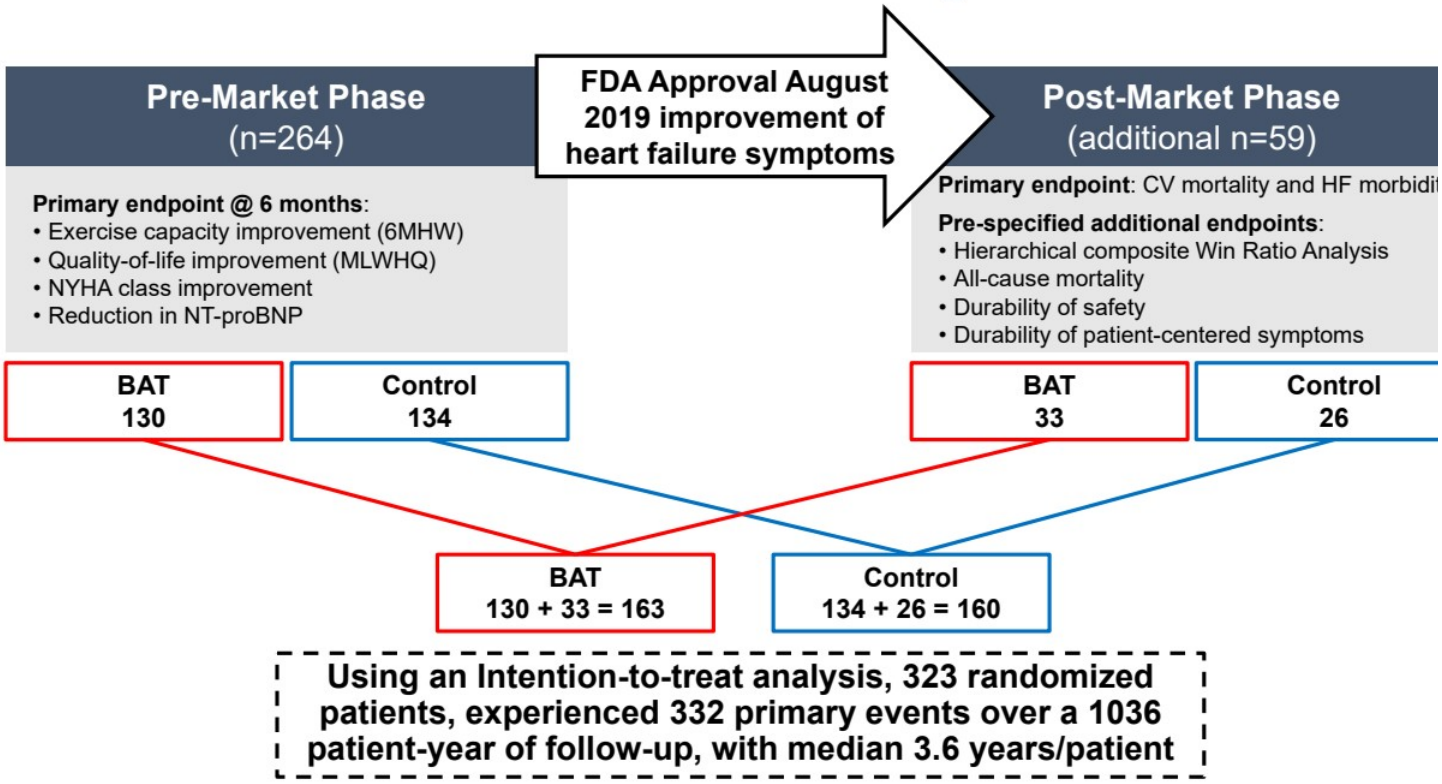
Groups: - BAT plus optimal medical management (**BAT group**)
- Optimal medical management alone (**Control group**)

Sites: 103 US centers and 5 United Kingdom centers

Eligibility criteria:
- NYHA Class III or Class II (with a recent history of Class III)
- Left ventricular EF ≤ 35%
- 6MHW 150 – 400 m
- HF Hospitalization or NT-proBNP > 400
- Stable optimal medical management ≥ 4 weeks
- No Class of Recommendation I indication for CRT
- NT-proBNP < 1600 pg/ml

Designated by FDA as Breakthrough Device in HFrEF

BeAT-HF Trial Design



BeAT-HF Baseline Characteristics

Baseline Characteristics	BAT (n=163)	Control (n=160)
Age at Screening (years)	63 ± 11	63 ± 10
Female	28 (17.2%)	35 (21.9%)
Race		
White	120 (73.6%)	116 (72.5%)
Black or African American	29 (17.8%)	24 (15.0%)
Asian	3 (1.8%)	2 (1.3%)
Other/Unknown	11 (6.7%)	18 (11.3%)
SBP (mmHg)	120 ± 16	121 ± 16
DBP (mmHg)	74 ± 10	73 ± 10
HR (bpm)	75 ± 10	75 ± 11
BMI (kg/m2)	31 ± 5	31 ± 5
eGFR	62.5 ± 16.3	61.1 ± 18.9
NYHA: Class III	155 (95.1%)	151 (94.4%)
LVEF (%)	27 ± 6	28 ± 6
6 Minute Walk (m)	314 ± 66	300 ± 71
QOL	53 ± 24	51 ± 24
NT-proBNP (pg/mL)	736 (474, 1057)	704 (442, 1044)
LBBB	4 (2.5%)	2 (1.3%)
At Least One HF Hospitalization	66 (40.5%)	79 (49.4%)
Number of HF Hospitalizations	0.6 ± 0.9	0.7 ± 0.8

No significant difference between BAT and Control

BeAT-HF Baseline Characteristics

Baseline Characteristics	BAT (n=163)	Control (n=160)
Coronary Heart Disease		
Coronary Artery Disease	104 (63.8%)	107 (66.9%)
Myocardial Infarction	89 (54.6%)	97 (60.6%)
CABG	35 (21.5%)	44 (27.5%)
PCI	72 (44.2%)	72 (45.0%)
Cardiac Arrhythmia		
Bradycardia	19 (11.7%)	18 (11.3%)
Tachycardia	54 (33.1%)	56 (35.0%)
Atrial Fibrillation	53 (32.5%)	66 (41.3%)
Stroke or TIA	29 (17.8%)	37 (23.1%)
Chronic Kidney Disease	45 (27.6%)	43 (26.9%)
Diabetes		
Type I	0 (0.0%)	2 (1.3%)
Type II	74 (45.4%)	80 (50.0%)

No significant difference between BAT and Control

BeAT-HF Baseline HF Treatment

Baseline Medications	BAT (n=163)	Control (n=160)
Number of Meds	4.0 ± 1.3	4.1 ± 1.5
ACE-I / ARB / ARNI	143 (88%)	129 (81%)
ARNI	57 (35%)	43 (27%)
Beta-Blocker	152 (93%)	147 (92%)
MRA	74 (45%)	64 (40%)
SGLT2i	1 (0.6%)	0 (0%)
Diuretic	138 (85%)	139 (87%)
Ivabradine	4 (2.5%)	9 (5.6%)
ICD	125 (77%)	127 (79%)
Pacemaker (non-ICD)	3 (1.8%)	2 (1.3%)
CRT	4 (2.5%)	5 (3.1%)
Other cardiac device (e.g., CardioMEMS)	8 (4.9%)	4 (2.5%)

No significant difference between BAT and Control

Study Endpoints

Primary Endpoint

Cardiovascular (CV) Mortality And Heart Failure (HF) Morbidity

- Assessed using a negative binomial model
- Includes recurrent HF morbidity events
- Pre-specified event–driven (n=320 events minimum)

CV Mortality:

- Cardiovascular deaths
- LVAD and heart transplants

HF Morbidity:

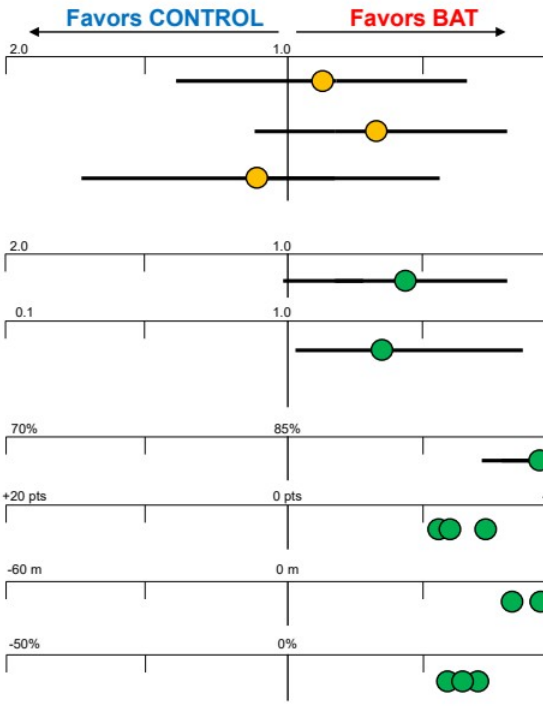
- Non-elective HF hospitalization
- HF emergency room visit

Pre-specified additional endpoints

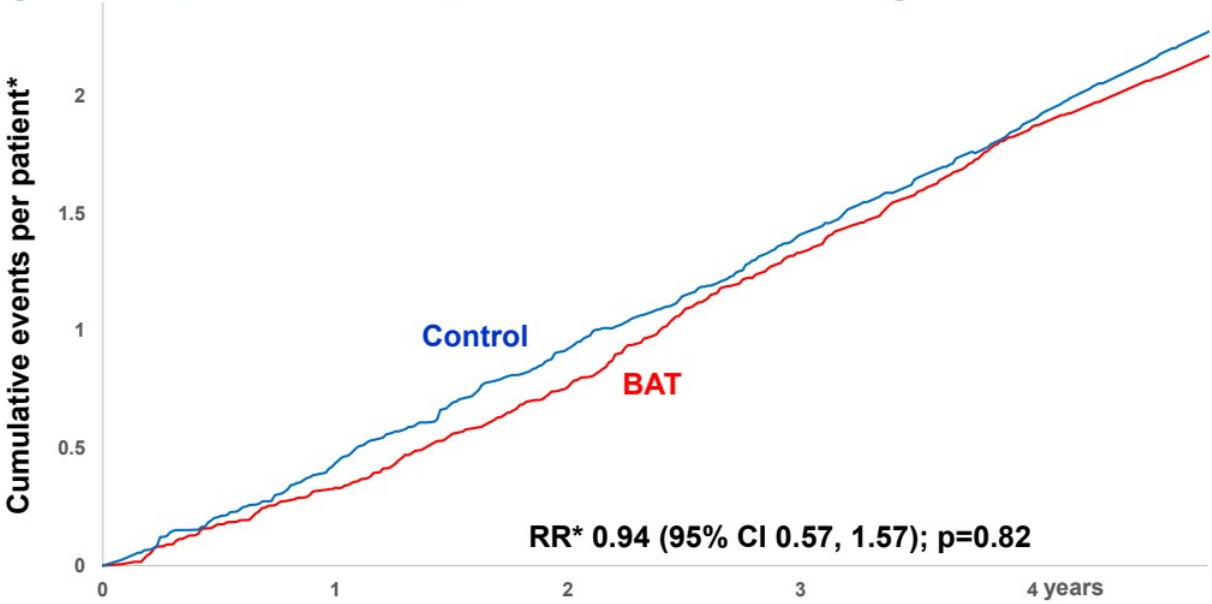
- Hierarchical composite analysis usir Win Ratio
- All-cause mortality
- Durability of safety
- Durability of improved patient-centered symptom status
  - Quality of Life (MLWHFQ)
  - Exercise Capacity (6MHWD)
  - Functional Status (NYHA Class

BeAT-HF Summary of Key Evidence

	Description		Favors CONTROL / Favors BAT
Primary endpoint	**Composite CV Mortality and HF Morbidity**	Rate Ratio = 0.94	
	CV Mortality (CV death, LVAD, heart transplant)	Hazard Ratio = 0.73	
	HF Morbidity (Heart failure hospitalization, ER/ED visit)	Rate Ratio = 1.08	
Additional Analyses	**All-cause Mortality** (death, LVAD, heart transplant)	Hazard Ratio = 0.66	
	Hierarchical Win Ratio (CV mortality, HF morbidity, QOL)	Win Ratio = 1.26	
Long-term Safety	**Related MANCE-free Rate*** *Major Adverse Neurologic and Cardiac Events	96.9%	
Long-term Symptom Improvement	**Quality of Life – MLWHF** (6 / 12 / 24 Month)	-13 / -8 / -10	
	Exercise Capacity – 6MHW (6 / 12 Month)	+55 / +44	
	Functional Status – NYHA Class % Improved (6 / 12 / 24 Month)	30% / 32% / 27%	



Primary Composite Endpoint: CV Mortality and HF Morbidi



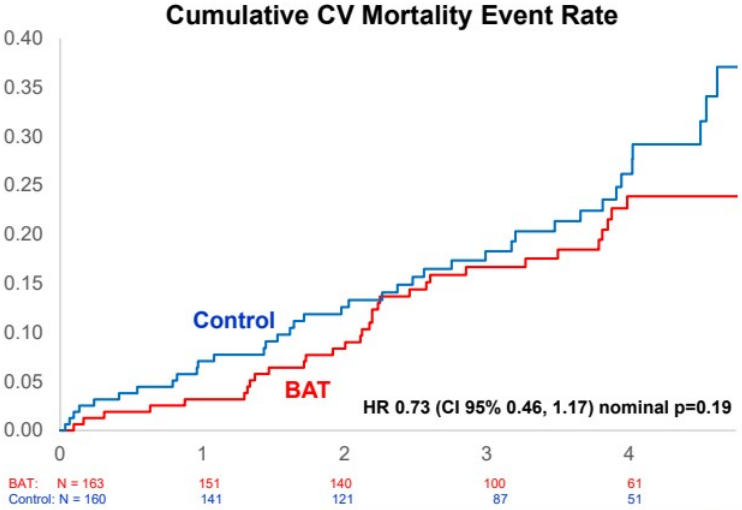
BAT:	N = 163	151	140	100	61
Control:	N = 160	141	121	87	51

No statistically significant difference between BAT and Control

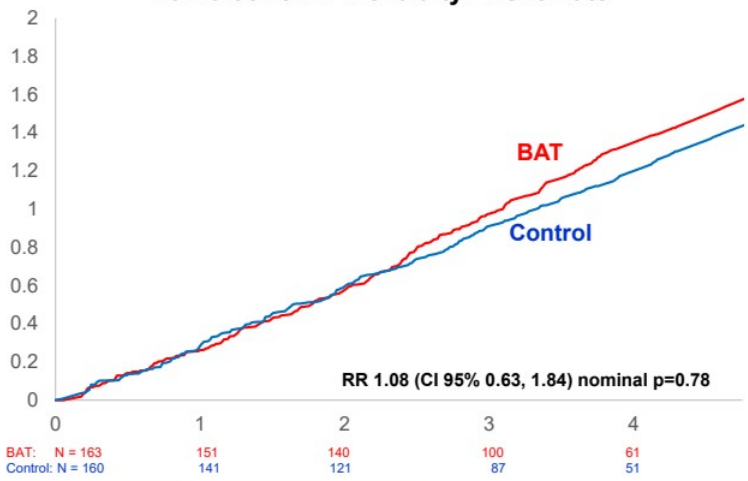
* Cumulative events per patient and rate ratio (RR) of treatment / control and 95% confidence interval estimated by negative binomial method

Components of Primary Endpoint

Cumulative CV Mortality Event Rate



Cumulative HF Morbidity Event Rate



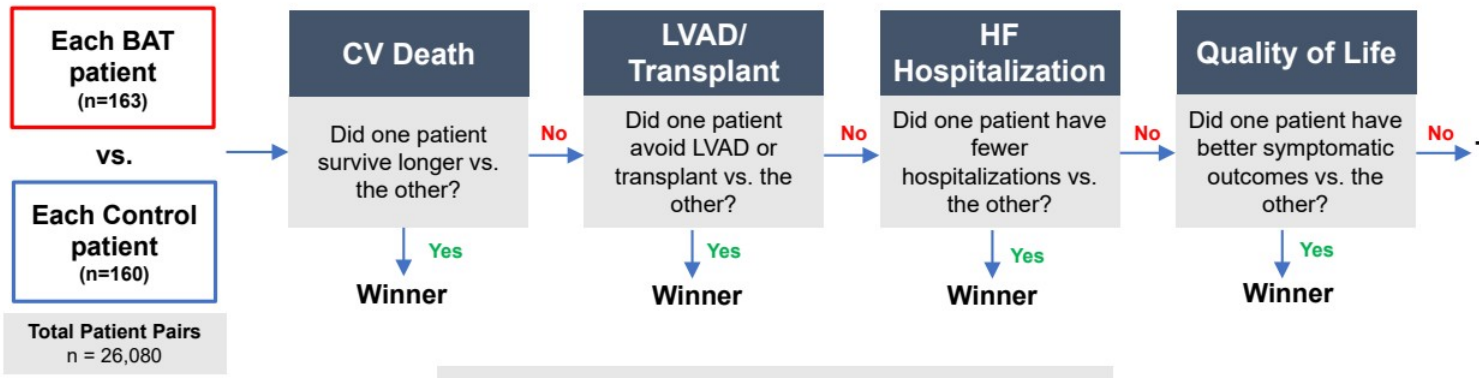
Event rate per 100 years (events / patient-years at risk)	BAT	Control
CV Mortality	5.8 (32 / 544)	7.9 (39 / 492)
HF Morbidity	26.6 (145 / 544)	23.6 (116 / 492)

No statistically significant difference between BAT and Control

Hierarchical Composite Using Win Ratio Analysis

Rationale:

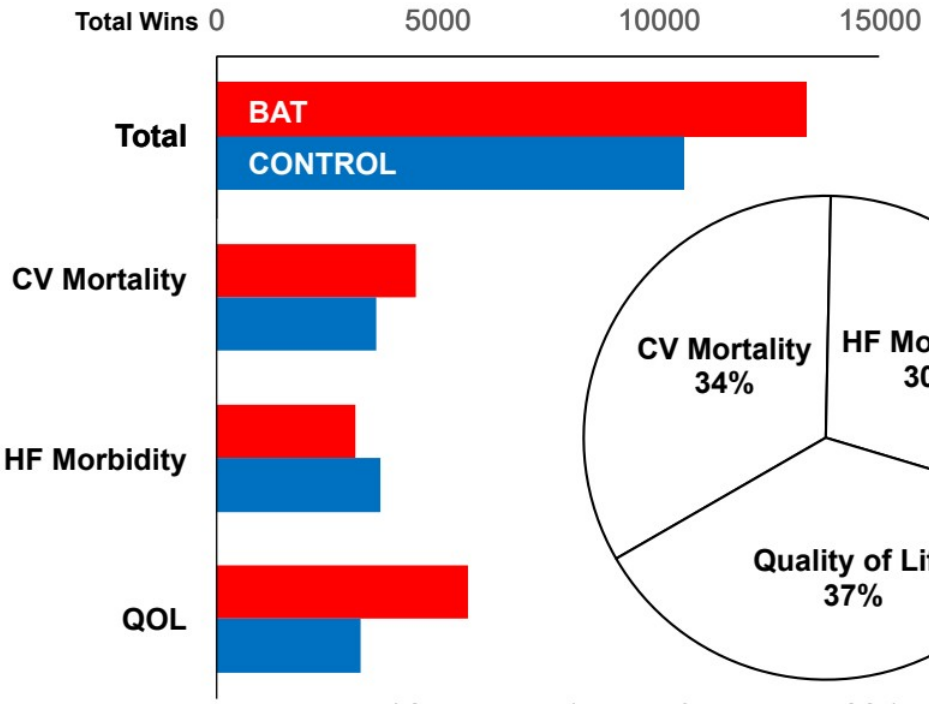
- CV Mortality + HF Morbidity: 40% of patients contributed to the end point
- Win ratio: 100% of patients contribute to the end point
- Used in many recent heart failure randomized controlled trial, drugs and devices



$$\text{Win Ratio} = \frac{\text{Total wins for BAT}}{\text{Total wins for Control}}$$

Stats: Finkelstein - Schoenfeld

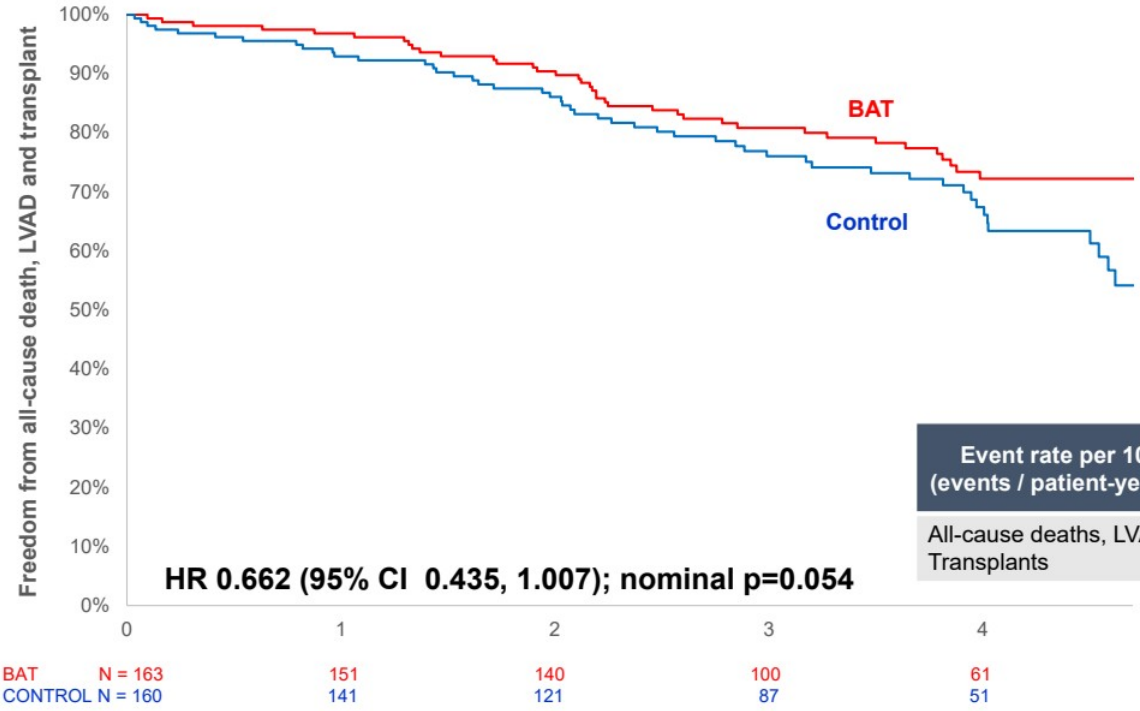
Hierarchical Composite Using Win Ratio Analysis



Win Ratio = 1.26
(1.02, 1.58)
nominal p-value = 0.04

* Sensitivity Test (All time M&M + 24 Month QOL) Win Ratio = 1.34 (95% CI 1.07, 1.68); nominal p=0.01

Freedom From All-cause Death, LVAD, and Transplant



BAT resulted in a 34% reduction in relative risk

Event rate per 100 years (events / patient-years at risk)	BAT	Cont
All-cause deaths, LVAD, Heart Transplants	7.0 (38 / 544)	10.4 (51 / 4

BAT	N = 163	151	140	100	61
CONTROL	N = 160	141	121	87	51

* Curves estimated using Kaplan-Meier method. Hazard ratio and p-value from Cox proportional hazards model.

Durable Safety Profile: MANCE*

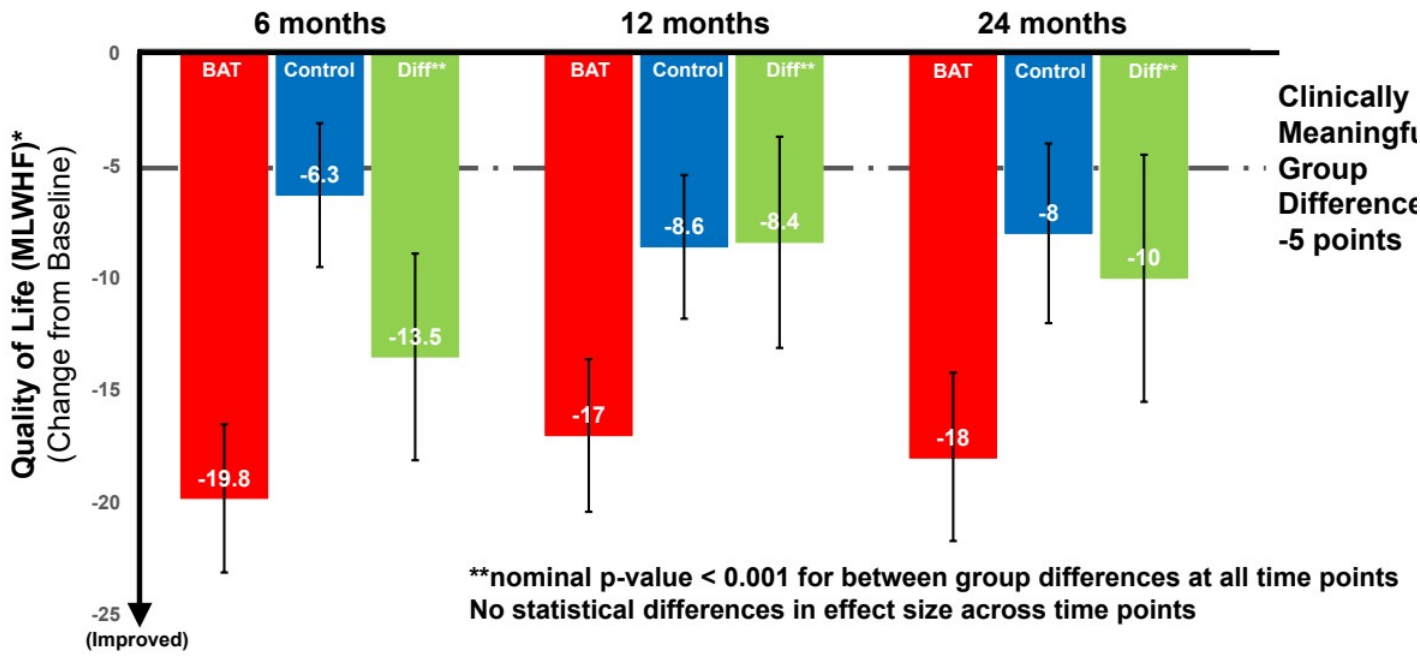
(Major Adverse Neurological or Cardiovascular system or procedure-related event rate)

Number of Subjects	Number of Subjects MANCE-Free	MANCE-Free Rate	One-Sided 95% Lower Bound	P-value**
159	154	96.9%	93.5%	<0.001

Device was surgically implanted in an outpatient procedure, totally extravascula

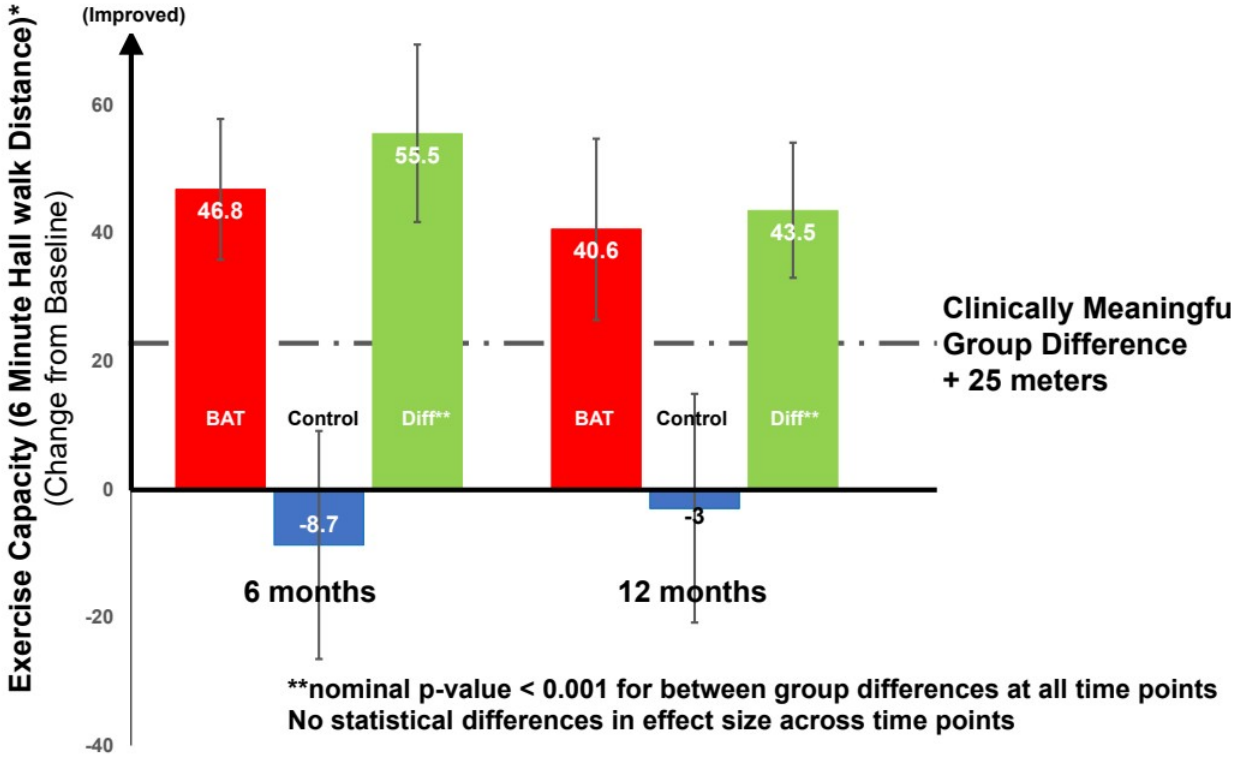
* Major Adverse Neurological or Cardiovascular system or procedure-related event rate
**Clopper-Pearson exact binomial method. One-sided hypothesis test p-value versus 85% performance goal.

Durable Improvement in Quality of Life (MLWHF)



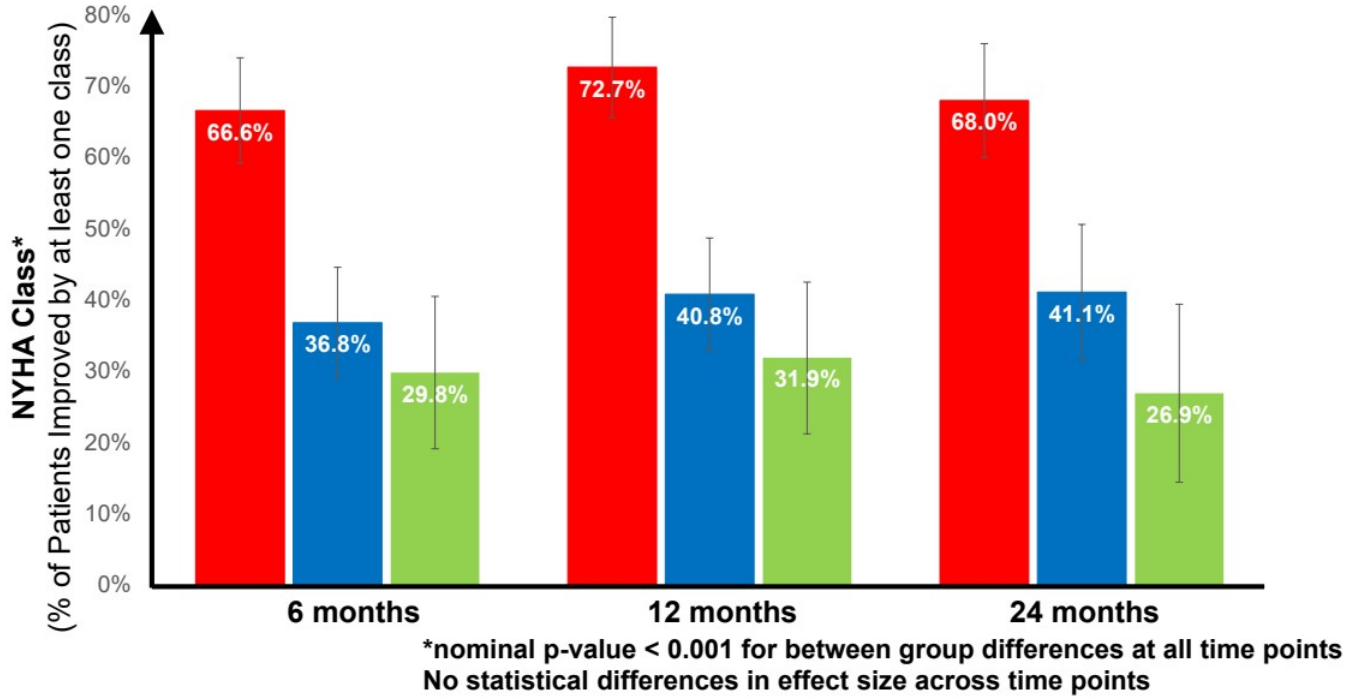
*Statistics are estimated mean improvement and 95% confidence interval from repeated measures model
**From generalized estimating equation repeated measures model with covariate for baseline value

Durable Improvement in Exercise Capacity (6MHWD)



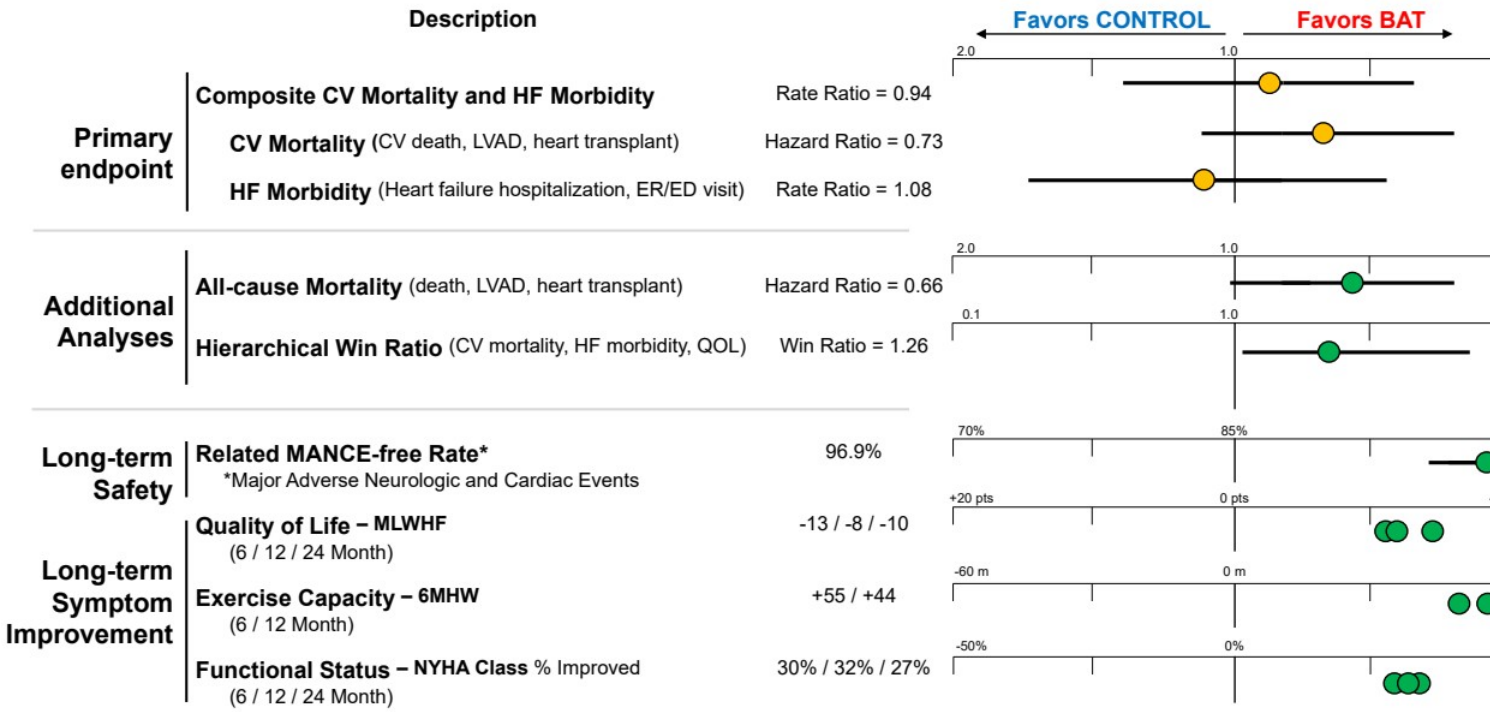
*Statistics are estimated mean improvement and 95% confidence interval from repeated measures model
**From generalized estimating equation repeated measures model with covariate for baseline value

Durable Improvement in Functional Status (NYHA Class)



*Statistics are estimated proportion and 95% confidence interval from repeated measures model
**From generalized estimating equation repeated measures model with covariate for baseline value

BeAT-HF Summary of Key Evidence



Totality of Data Favors BAT

Conclusion

Totality of evidence indicates that BAT is a safe, effective and durable treatment for patients with heart failure with reduced ejection fraction

Additional Excerpts from the Symposium

CVRx-Sponsored Lunch Symposium at 12:15 – 1:15 pm
Grand Ballroom A-B, Concourse Level

an in-depth discussion on the findings from BeAT-HF and potential confounders (COVID-19, Medications) and real-world experience using Barostim

Presented by:

- **William T. Abraham**
- **JoAnn Lindenfeld**
- **Patrick J. McCann**
- **Michael R. Zile**

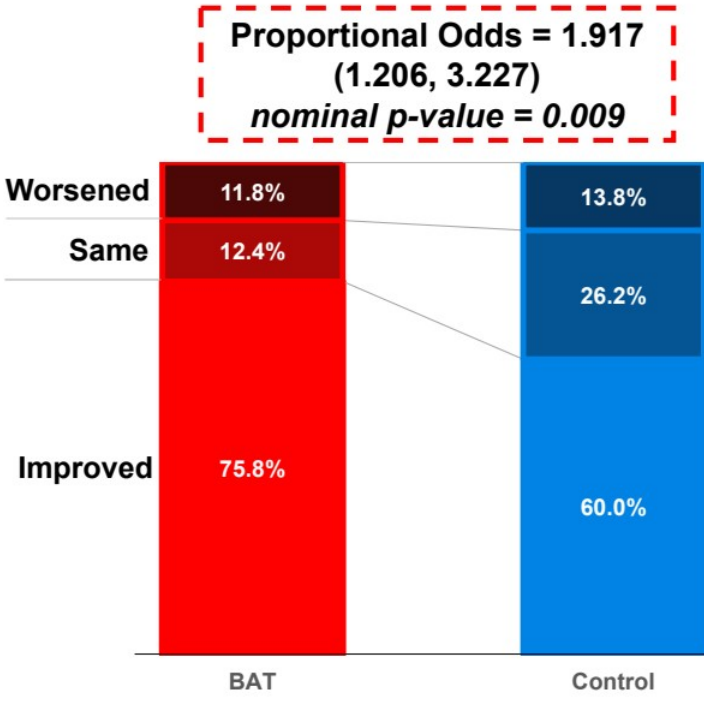
CRF THT

Clinical Stability Analysis *

Improved:
- Subject does not meet any worsening category AND
- Fewer HF hospitalizations in 12 months post-enrollment vs 12 months pre-enrollment,
- OR improved NYHA class at 12 months vs. baseline;

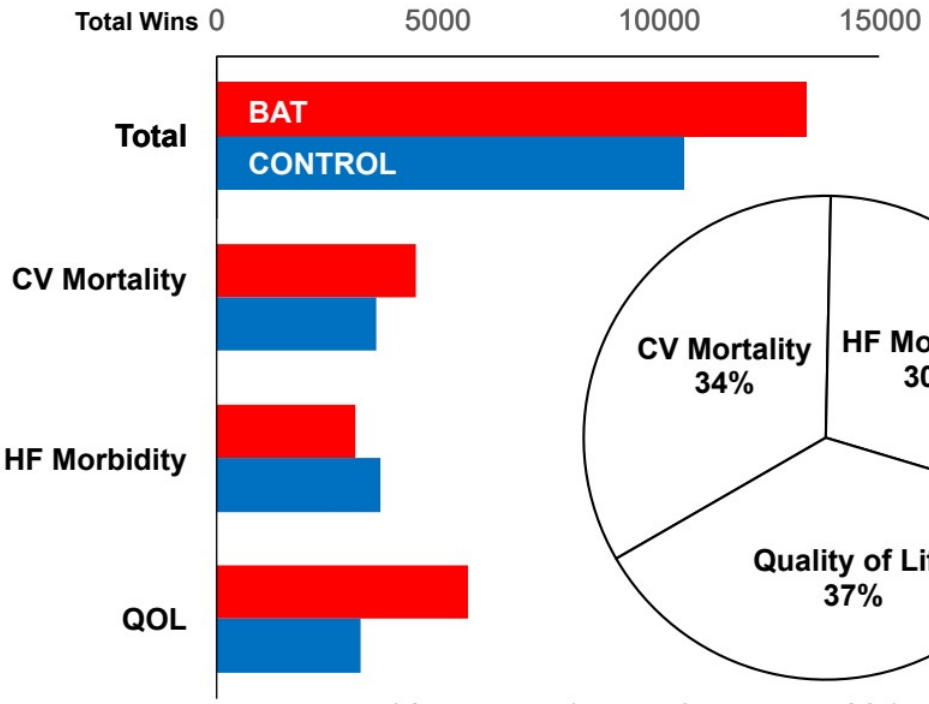
Same:
- Neither worsened nor improved
- AND evaluable for both HF hospitalizations and NYHA;

Worsened:
- Died prior to 12 months,
- OR more HF hospitalizations in 12 months post-enrollment as compared to 12 months pre-enrollment,
- OR higher NYHA class at 12 months vs. baseline



*** Similar to that used in: Packer et al, Circulation. 2021;143:326–336, EMPEROR-Reduced Trial**

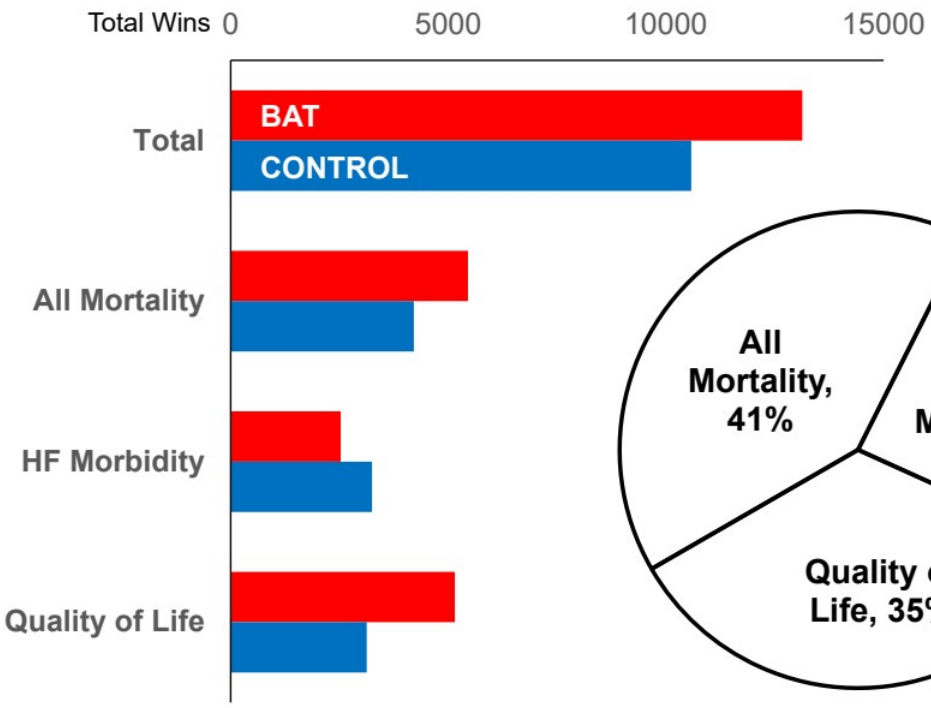
Hierarchical Composite Using Win Ratio Analysis



Win Ratio = 1.26
(1.02, 1.58)
nominal p-value = 0.04

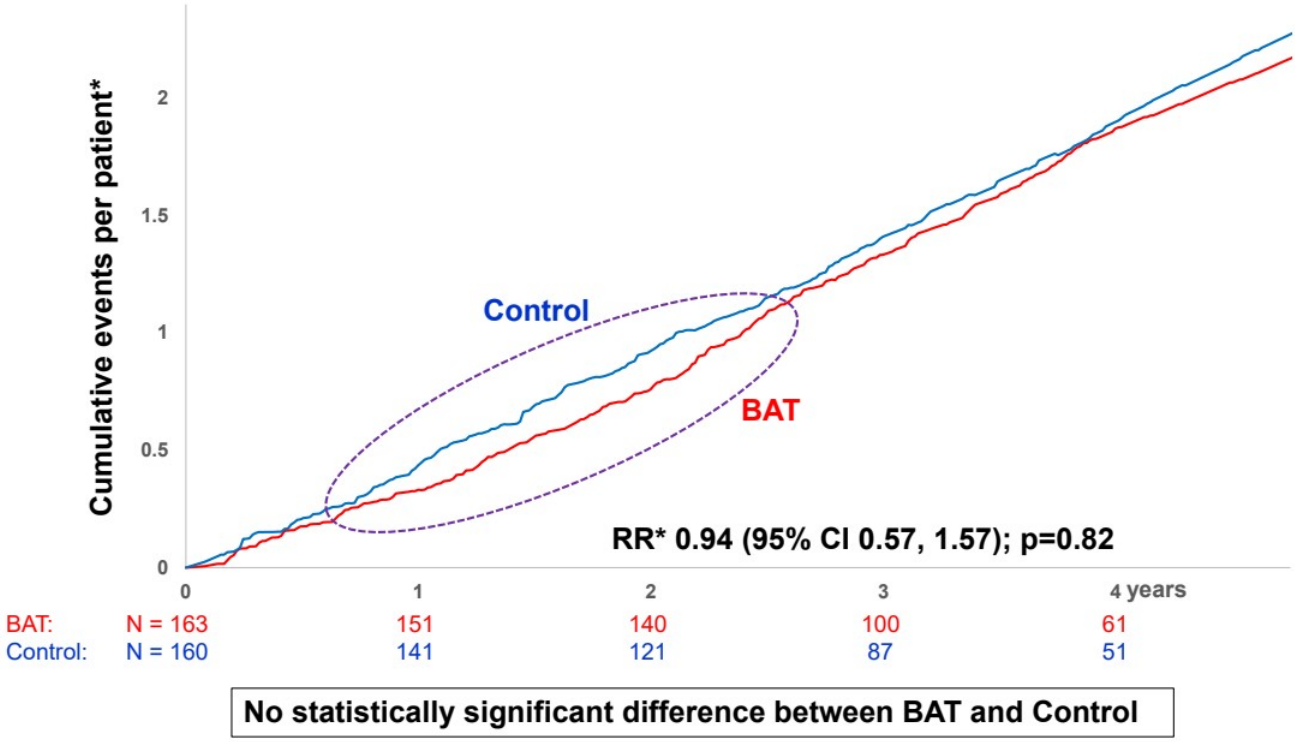
* Sensitivity Test (All time M&M + 24 Month QOL) Win Ratio = 1.34 (95% CI 1.07, 1.68); nominal p=0.01

Sensitivity Analysis – All-Cause Mortality Win Ratio



Win Ratio = 1.27
(1.02, 1.59)
nominal p-value = 0.04

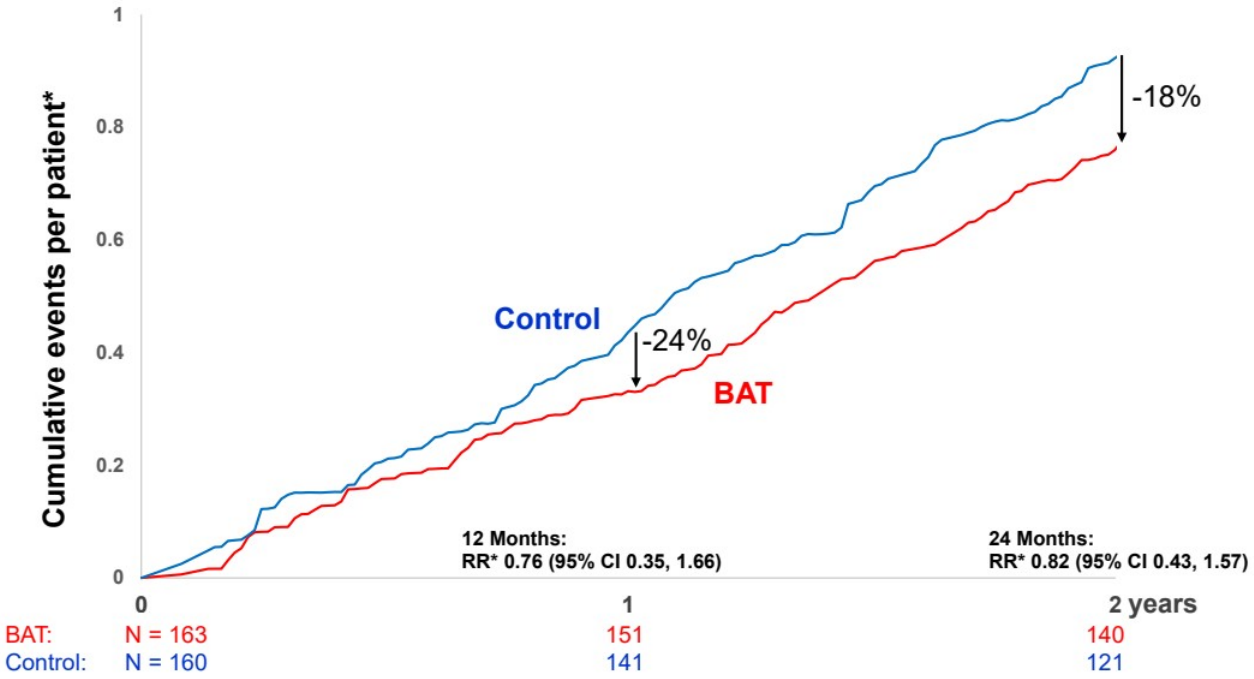
Primary Composite Endpoint: CV Mortality and HF Morbidity



No statistically significant difference between BAT and Control

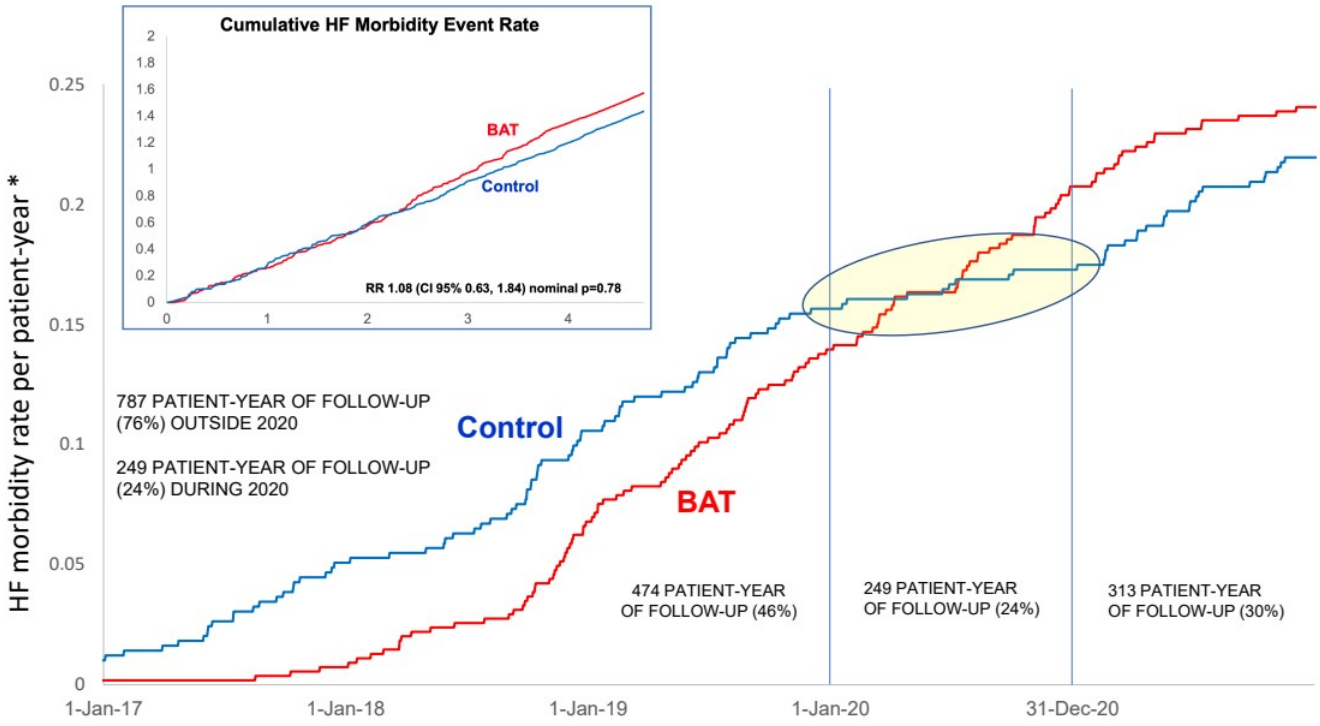
* Cumulative events per patient and rate ratio (RR) of treatment / control and 95% confidence interval estimated by negative binomial method

Primary Composite Endpoint at 12 and 24 Months



* Cumulative events per patient and rate ratio (RR) of treatment / control and 95% confidence interval estimated by negative binomial method

Impact of COVID-19 Pandemic on HF Morbidity



*Normalized by total patient-years of follow-up per arm (BAT: 544 patient-years, Control: 492 patient-years)

Potential Confounder: Impact of COVID Pandemic

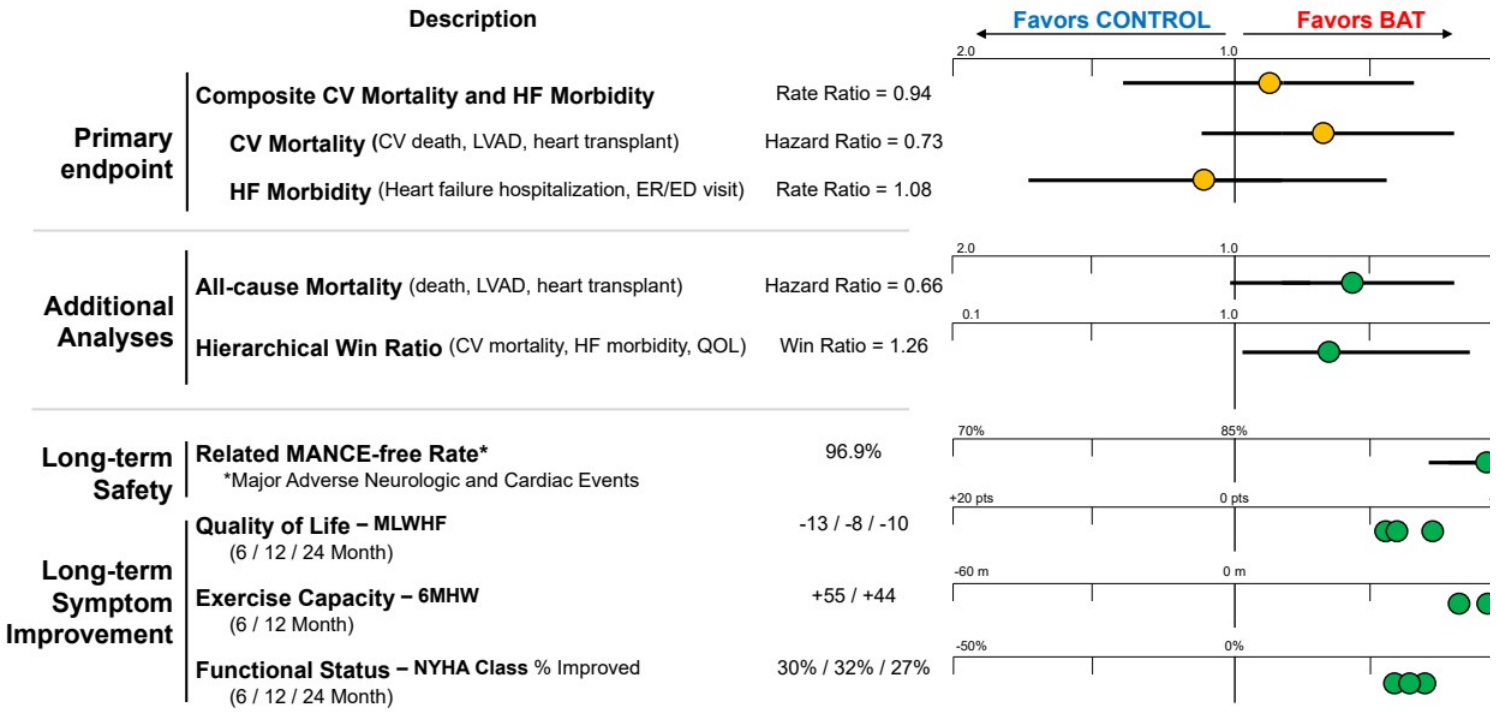
Heart Failure Morbidity

Time Period	BAT †	Control†
2020	0.28	0.07
2016, 2017, 2018, 2019, 2021, 2022	0.26	0.29

† Number of hospitalizations or emergency department visits for heart failure per patient-year of follow-up

- **COVID definitely impacted the results of the study.**
- **The COVID impact was differentially expressed more in the control group than in the BAT group.**
- **Why COVID has these differential effects has not been thoroughly investigated yet.**
- **Whether and to what extent COVID acted to limit our ability to identify an effect of BAT on the HF Morbidity awaits further analysis.**

BeAT-HF Summary of Key Evidence



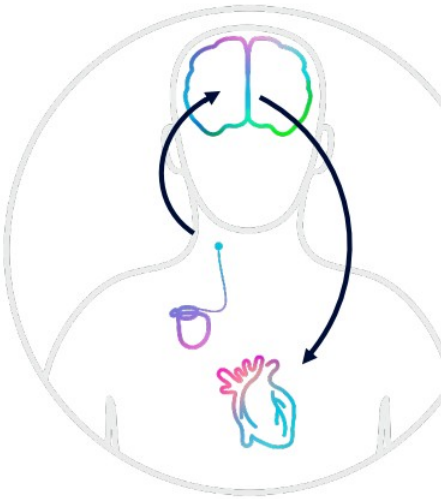
Totality of Data Favors BAT

Conclusion

Totality of evidence indicates that BAT is a safe, effective and durable treatment for patients with heart failure with reduced ejection fraction

Key takeaways

- Barostim is currently FDA-approved for the improvement of heart failure symptoms based on the pre-market phase of BeAT-HF at 6 months.
- The post-market phase of BeAT-HF confirmed the long-term durability of safety and symptomatic improvements, and the sustainability of the extent of the improvements.
- The reduction of all-cause death, LVAD and heart transplant is meaningful (34% reduction, nominal p-value 0.054).
- The pre-specified hierarchical composite endpoint was well balanced, and demonstrated meaningful benefit (Win ratio = 1.26, nominal p-value=0.04), stable over multiple sensitivity analyses



Next steps

- One or more manuscripts will be written by the executive steering committee for submission to peer-reviewed journals
- The PMA Clinical report is being prepared by CVRx to be submitted to FDA, to seek an expansion of the labeling, commensurate with the recommendation of the Executive Steering Committee of BeAT-HF. We agree with the committee that the totality of evidence supports the use of Barostim as a Treatment for heart failure

Questions?