

## Heart Failure 2020

Mrs Elizabeth Galle (EUD ID : 935058)  
Cvrx Inc.  
9201 West Broadway Avenue  
55445 - Minneapolis United States of America  
Email : lgalle@cvrx.com

Title : Impact of left ventricular ejection fraction and atrial fibrillation on Baroreflex Activation Therapy  
Topic : 10.4.8 - Devices for Autonomic Modulation  
Category :Clinical  
Option : Oral Presentation  
Funding Acknowledgements : CVRx Inc.

M. Zile<sup>1</sup>, W. Abraham<sup>2</sup>, F. Weaver<sup>3</sup>, F. Zannad<sup>4</sup>, E. Galle<sup>5</sup>, T. Rogers<sup>6</sup>, J. Lindenfeld<sup>7</sup> - (1) Medical University of South Carolina, Department of Medicine, Division of Cardiology, Charleston, United States of America (2) The Ohio State University, Division of Cardiovascular Medicine, Columbus, United States of America (3) University of Southern California, Division of Vascular Surgery and Endovascular Therapy, Keck School of Medicine, Los Angeles, United States of America (4) University of Lorraine, Clinical Investigation Center, Nancy, France (5) CVRx Inc., Minneapolis, United States of America (6) NAMSA Inc., Statistics, Minneapolis, United States of America (7) Vanderbilt University Medical Center, Heart and Vascular Institute, Nashville, United States of America

Background: Despite available treatments, one third of heart failure (HF) patients with a reduced left ventricular ejection fraction (LVEF) remain in NYHA Class III. New treatments available include baroreflex activation therapy (BAT). No results have been published on its effectiveness in patients across varying levels of LVEF and history of atrial fibrillation (AF).

Purpose: Demonstrate the benefit of BAT in NYHA Class III HF patients by LVEF and AF status.

Methods: A multicenter trial conducted in subjects currently or recently with NYHA class III symptoms, LVEF  $\leq$  35%, stable optimal guideline directed therapy (GDT) for HF for at least 4 weeks, no class-I indication for cardiac resynchronization therapy, and NT-proBNP < 1600 pg/ml, randomized subjects 1:1 to BAT plus GDT or GDT alone (Control). Change from baseline to 6 months data was analyzed across LVEF and AF in 120 BAT and 125 Control subjects for 6-minute hall walk distance (6MHW), Minnesota Living with HF Questionnaire (QOL), NYHA Class and NT-proBNP.

Results: BAT significantly improves all outcomes in the LVEF / AF groups as shown below. BAT is the only device indicated in this HF population for patients who have AF or LVEF < 25%.

Conclusion: BAT is effective in all groups studied and should be considered an effective treatment for these patients.

#### Six Month Improvement by AF and LVEF

6M Improvement Between the Arms	All subjects	History of AF	No History of AF
All subjects	BAT N=120 Control N=125	BAT N=33 Control N=54	BAT N=87 Control N=71
6MHW (meters)	60*	66*	57*
MLWHF (points)	-14*	-12*	-16*
NYHA (% improved)	34%*	27%*	37%*
NT-proBNP (% change)	-25%*	-23%	-25%*
LVEF < 25%	BAT N=30 Control N=28	BAT N=5 Control N=8	BAT N=25 Control N=20
6MHW (meters)	76*	127*	76*
MLWHF (points)	-15*	-16*	-15*
NYHA(% improved)	31%*	10%	38%*
NT-proBNP (% change)	-37%*	-64%*	-27%
LVEF 25%- 35%	BAT N=90 Control N=97	BAT N=28 Control N=46	BAT N=62 Control N=51
6MHW (meters)	56*	59*	51*
MLWHF (points)	-13*	-12*	-15*
NYHA(% improved)	35%*	30%*	37%*
NT-proBNP (% change)	-20%	-11%	-24%

Change from baseline estimates were adjusted for baseline value. \*p<0.05

#### » Rules and Regulations