THE LIBERATE STUDY

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A multicenter, multinational randomized controlled trial of Zephyr® Endobronchial Valves (EBV) in patients with heterogenous emphysema and little to no collateral ventilation

"The benefits are comparable to those seen with LVRS (lung volume reduction surgery) but with a reduction in post-procedure morbidity."*

Methods & Endpoints

- First multicenter to evaluate effectiveness and safety of Zephyr Endobronchial Valves in patients with little to no collateral ventilation (CV) out to 12 months.
- 190 subjects with hyperinflation (RV, 225% pred.; FEV_1, 27% pred.; DLCO, 34% pred.) randomized 2:1 (128 Zephyr EBV: 62 SoC).

*SOURCE: Criner G et al. Am J Resp Crit Care Med 2018; 198(9): 1151-1164

zephyr® valve

Study Design

909 Subjects Consented

719 Subjects Excluded
- 13 withdrew consent
- 706 screen failures
  - 65 no eligible CV-lobe
  - 280 heterogeneity/destruction score
  - 156 PFTs/lung volumes
  - 145 medical history, age, BMI, smoking history
  - 49 blood chemistry
  - 11 other

190 Subjects Randomized

Zephyr® EBV (n=128)	Standard of Care (SoC) (n=62)
• 2 withdrew consent • 4 died • 1 excluded for medical reasons	
121 Active Subjects at 45 Days	**62 Active Subjects at 45 Days**
45-day Follow-up	
• 1 died	• 1 died • 2 excluded for medical reasons
120 Active Subjects at 6 Months	**59 Active Subjects at 6 Months**
6-month Follow-up	
• 1 unwilling to return for follow-up visits	
119 Active Subjects at 12 Months • 2 missed 12-month visit • 2 not evaluated due to ongoing adverse events (AEs) – both subsequently died in year 2	**59 Active Subjects at 6 Months**
12-month Follow-up	

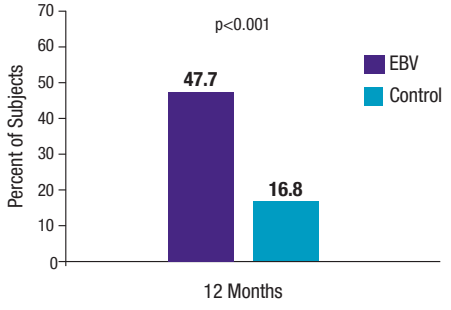
117 in Long-term Follow-up

43 Active Crossover Subjects
- 8 pending crossover procedures
- 7 excluded for medical reasons
- 1 died

Results in ITT population

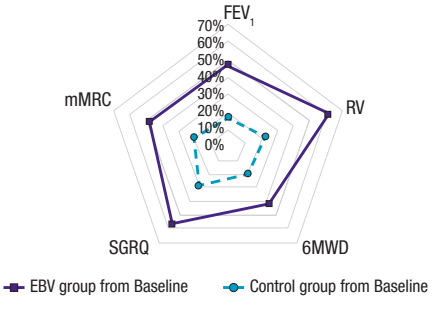
Primary Endpoint Responder Analysis

Percent of Subjects with FEV_1 Change of ≥15%



Other Responder Analysis

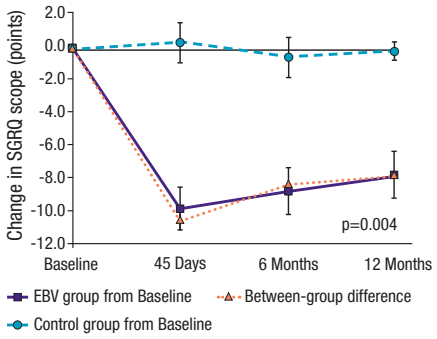
Proportion of Patients Achieving MCID



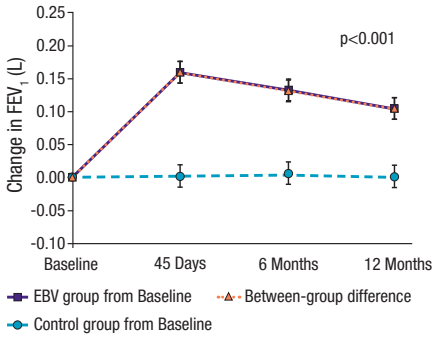
*SOURCE: Criner G et al. Am J Resp Crit Care Med 2018; 198(9): 1151-1164

Secondary Endpoints

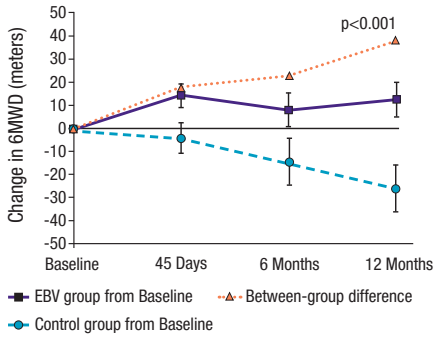
St. George's Resp Questionnaire (points)



FEV_1 (L)



6MWD (meters)



Safety: Pulmonary Serious Adverse Events (SAEs) Occurring in at Least 3.0% of Subjects in Either Group

	Treatment Period (0 – 45 Days)		Longer-Term Period (46 Days – 1 Year)	
	EBV (n=128)	SoC (n=62)	EBV (n=122)	SoC (n=62)
Death	3.1%	0%	0.8%	1.6%
Pneumothorax	26.6%*	0%	6.6%	0%
COPD exacerbation	7.8%	4.8%	23.0%	30.6%
Pneumonia	0.8%	0%	5.7%	8.1%
Respiratory failure	1.6%	0%	0.8%	3.2%

*Statistically different from SoC

- Increased SAE rate with EBV treatment compared to SoC in the short-term (first 45 days post-procedure)
- Reduced SAE rate long-term (46 days to 12 months) with EBV treatment compared to standard of care
- 5 of the 8 subjects experiencing a pneumothorax in the longer-term period had recently undergone a secondary bronchoscopy for valve replacement and/or removal

Conclusion

Zephyr® Endobronchial Valve treatment in carefully selected patients with little or no collateral ventilation in the target lobe provides clinically meaningful and statistically significant benefits in lung function, exercise tolerance, dyspnea, and quality of life over current standard of care medical therapy out to at least 12 months.

*SOURCE: Criner G et al. Am J Resp Crit Care Med 2018; 198(9): 1151-1164

United States

Brief Statement: The Pulmonx Zephyr® Endobronchial Valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; Patients with evidence of active pulmonary infection; Patients with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); Patients with known allergies to silicone; Patients who have not quit smoking; Patients with large bullae encompassing greater than 30% of either lung. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial Valve System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

Brief Statement: The Chartis® System is indicated for use by bronchoscopists during a bronchoscopy in adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD), in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information. The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances. Use is restricted to a trained physician. Prior to use, please reference the Chartis System Instructions for Use/ User Manual for more information on indications, contraindications, warnings, all precautions, and adverse events.

Caution: Federal law restricts this device to sale by or on the order of a physician.

International

Brief Statement: The Zephyr® Endobronchial Valve is an implantable bronchial valve intended to control airflow in order to improve lung functions in patients with hyperinflation associated with severe emphysema and/or to reduce air leaks. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; Evidence of active pulmonary infection; Patients with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); Patients with known allergies to silicone; Patients who have not quit smoking. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

Brief Statement: The Chartis® System is indicated for use by bronchoscopists during a diagnostic bronchoscopy in adult patients with Chronic Obstructive Pulmonary Disease (COPD) and emphysema in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information. The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances. Use is restricted to a trained physician. Prior to use, please reference the Chartis System Instructions for Use/User Manual for more information on indications, contraindications, warnings, all precautions, and adverse events.

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