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## Five-Year Durability of Zephyr Valves in Patients with Severe Emphysema

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Background: Benefits of BLVR with Zephyr valves (EBV) vs a control group with severe emphysema have been shown out to 12 months. Prospective, long-term data beyond 1 year are lacking.

Objective: Assess long-term durability and safety of EBV in patients treated in the LIBERATE Study (NCT 01796392).

Methods: EBV treated patients evaluated annually for 5 years to assess FEV1 change from Baseline to subsequent years plus all adverse events.

Results: Improvement from Baseline in FEV1 was maintained out to 5 years with change from Baseline: Mean $\pm$ SD(n) of 109 $\pm$ 201mL(115), 91 $\pm$ 203mL(90), 53 $\pm$ 212mL(74), 121 $\pm$ 452mL(44), 79 $\pm$ 275mL(40) at Year1, Year 2, Year 3, Year 4, and Year 5, respectively. Corresponding responder rates (FEV1 improvement  $\geq$ 15%) were 49.6%, 48.9%, 35.1%, 36.4%, and 30.0%, respectively. The incidence of respiratory AEs and SAEs during post-procedure Years 2 through 5 are generally similar or lower than those observed during post-procedure Year 1. Most common SAEs beyond Year 1 were COPD exacerbations (range: 13.5 to 23.1%), pneumonia (3.8 to 9.6%), respiratory failure (1.8 to 11.5%), and pneumothorax (1.3 to 3.6%). There were no new types of respiratory SAEs and no increase in the frequency of respiratory SAEs compared to prior years. There were 39 deaths after Year 1 to Year 5.

Conclusion: EBV treatment resulted in durable improvements in lung function out to at least 5 years with an acceptable safety profile. Even in the absence of a control group beyond year 1, the continued improvement over baseline would be considered an advantage over maximal medical treatment alone given the known decline in lung function over time.