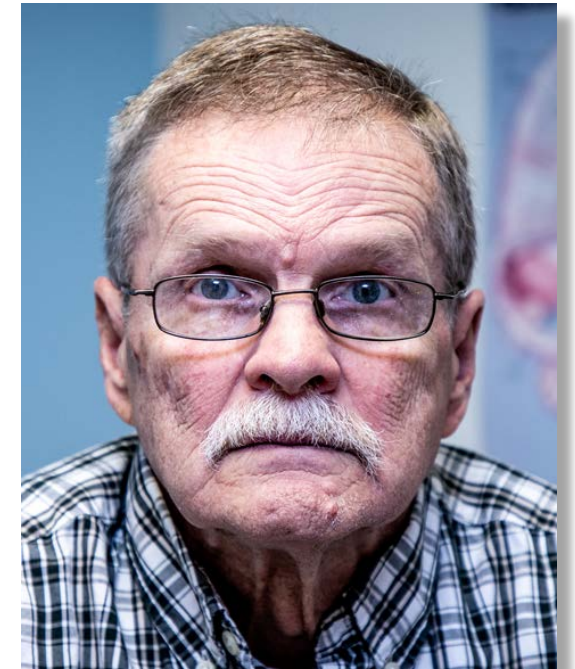


Clinical Context

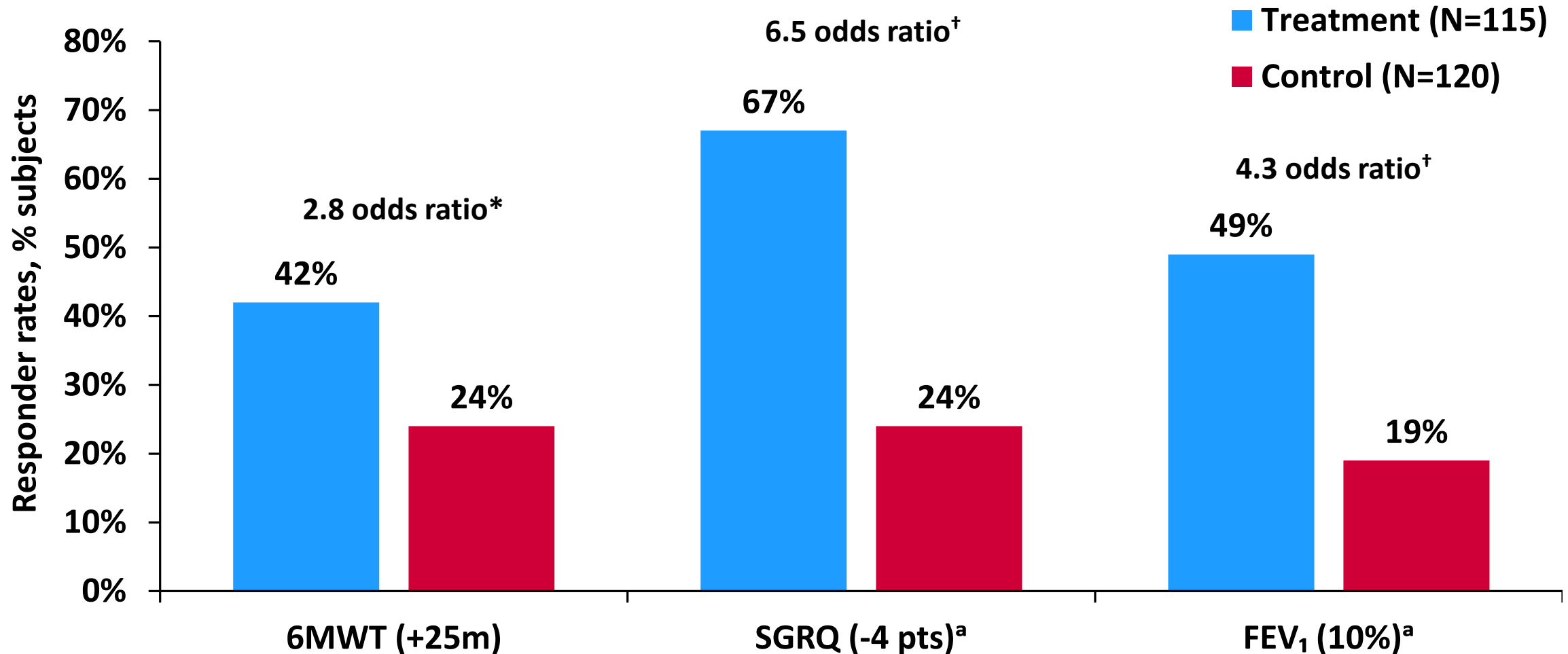
Frank Scieurba, MD

Professor of Medicine and Education
University of Pittsburgh Medical Center

Severe Emphysema Patients With Severe Hyperinflation Have Poor Quality of Life



MCID Responder Analysis Demonstrates Substantial Clinical Benefit in Subjects with RV $\geq 225\%$ Predicted



^a Adjusted mean responder rates. *Nominal p-value <0.01 unadjusted for multiplicity. [†]Nominal p-value <0.0001 unadjusted for multiplicity.

Note: Figure was not provided within the PMA; however, underlying information / analysis was included.

Risks Associated With ELEVAIR™ System Are Manageable

- Manageable, well-characterized safety profile
- Device and procedure-related complications decrease over time
- Mortality rates were similar in the treatment and control groups in RENEW
- Safety profile similar in overall RENEW randomized population and subjects with RV $\geq 225\%$ predicted

Benefit-Risk Profile Assessment

Benefits

- Meaningful improvement in
- Lung function
 - Quality of life
 - Exercise capacity

Risks

- Increased risk of
- COPD exacerbation
 - Pneumonia
 - Pneumothorax
 - Bleeding

For Many Severe Emphysema Patients the Chance of Benefit Will Outweigh the Risks

Benefits

- Meaningful improvement in
- Lung function
 - Quality of life
 - Exercise capacity

>

Risks

- Increased risk of
- COPD exacerbation
 - Pneumonia
 - Pneumothorax
 - Bleeding

A substantial proportion of severe emphysema patients with RV >225% will likely perceive that the chance of benefit will outweigh the risks

The ELEVAIR™ System Provides a Meaningful Clinical Tool to Help Severe Emphysema Patients Who Are Seeking Options

