Clinical Context

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Severe Emphysema Patients With Severe Hyperinflation Have Poor Quality of Life
MCID Responder Analysis Demonstrates Substantial Clinical Benefit in Subjects with RV ≥225% Predicted

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 ≥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
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Risks
Increased risk of
• COPD exacerbation
• Pneumonia
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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