Post-Market Plan

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Post-Market Plan Elements

- Launch based on “Centers of Excellence” model
  - Treatment centers: offer therapy
  - Model treatment centers: offer therapy and host training program
- Comprehensive physician training program
  - Adapted based on post-market plan feedback
- Focused US post-approval study to collect additional safety and effectiveness data
- Ongoing European clinical study program and RENEW to collect long-term safety data
- Ongoing post-market surveillance program
Treatment Centers: Site Selection Criteria

- Hospitals have appropriate infrastructure, equipment, and personnel
- Sites and physicians have appropriate experience with interventional therapeutic procedures
- Sites and physicians commit to following PneumRx training curriculum and participating in US post-approval study
- Multidisciplinary approach to the treatment of patients with severe emphysema
Physician Training Program Concept

Qualified site selection

Online didactic training

In-person/peer-to-peer

On-site proctoring

Didactic test

Skills test

Sign-Off

Model treatment center
Patient selection
Case reviews
Hands-on

Monitoring

- Training program key performance indicators
- Site performance
Focused US Post-Approval Study

- PneumRx Goal: capture a significant majority of all patients treated in US in first years of commercialization.

  ≥300 patients enrolled

- Bilateral treatment

- 6- and 12-month follow-up

- Follow-up annually up to 3 years

- Endpoints evaluated at 12 months post baselines

- Proposed primary endpoint
  - $\Delta$ SGRQ

- Proposed secondary endpoints
  - $\Delta$ PFT (FEV1, RV, RV/TLC)
  - $\Delta$ exercise capacity (6MWT)

- Proposed primary safety endpoint
  - Rate of device- or procedure-related respiratory SAEs of interest
# Ongoing and Planned Clinical Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Expected treated patients, n</th>
<th>Expected enrollment completion</th>
<th>Follow-up period/visit schedule</th>
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<tbody>
<tr>
<td>US post-approval study (planned)</td>
<td>Minimum of 300</td>
<td>2021</td>
<td>3 yr/6 mo, annual thereafter</td>
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<td>US IDE studies</td>
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<td>RENEW Randomized</td>
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<td>2015</td>
<td>5 yr/Annual</td>
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<td>RENEW Roll-in</td>
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<td>Crossover</td>
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<td>2016</td>
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<td>EU registry</td>
<td>Maximum of 2000</td>
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<td>EU RCT (ELEVATE)</td>
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<td>2019</td>
<td>2 yr/Annual</td>
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International Post-Market Surveillance Program Is Ongoing

- The Endobronchial Coil System has been commercially available since 2010 and has been sold in 19 countries
- Expand on post-market surveillance program for Europe
- Cross-functional Vigilance Team, with members from Vigilance, Clinical, Medical, Regulatory, and Quality, will review
  - Published literature
  - AE/SAE reports from commercial experience, long-term follow-up from US IDE program, European studies, and future US post-approval study
  - Ad hoc reviews of solicited requests for information from a variety of sources
- Contribute to development of clinical practice guidelines
Physician Training Program Concept

- Qualified site selection
- Online didactic training
- Didactic test
- In-person/peer-to-peer
- Skills test
- On-site proctoring
- Sign-Off

Monitoring
- Training program key performance indicators
- Site performance
- Post-market surveillance data

Medical Education Department