Second Indication: Bronchiolitis (BRO) Overview

**Bronchiolitis is the leading cause of hospitalization for infants worldwide**

### Bronchiolitis Overview & Market Dynamics

- **~150,000 infant hospitalizations** per year in the US
- Significant impact on the elderly from equivalent viral infections with **177,000 hospitalizations** per year in the US
- **No drugs approved** for the treatment of BRO patients
- Standard of care in the hospital is oxygen and hydration

### Market Size

- AIT estimates US market size to be **>$2 B** and projects global market to be similar size to the US market with no competition
- AIT’s goal would be to reduce length of hospitalization in infants
- Elderly population trials to follow infants

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(2) Pelletier et al. Direct medical costs of hospitalizations in the United States, Pediatrics 2006
(3) CDC (due to RSV only)
(4) American Academy of Pediatrics
Completed Two Pilot Bronchiolitis Trials

Data from both Pilot Bronchiolitis trials demonstrated a significant reduction in length of hospital stay (LOS)

2014 Trial Design and Highlights

- Randomized, Prospective, Double-blind
- 43 patients (age: 2-12 months) with acute bronchiolitis (mostly due to RSV) and at least 36 weeks of gestation
- N=22: Supportive Care (O₂ & hydration)
- N=21: Supportive Care + 160 ppm NO for 30 minutes 5x/day up to 5 days
- Follow up visits 2, 3 & 4 weeks post discharge
- Single center at Soroka University Medical Center in Israel
- Data presented at ATS 2015 in an oral session
- Reduced length of hospital stay by ~24hrs in patients who stayed in the hospital for at least 24 hours
- No treatment related SAEs
- Improvements in composite endpoint (modified Tal score) and O₂ consistent with improvement in LOS

Published in the December 2017 Pediatric Pulmonology Journal[1]

Completed Two Pilot Bronchiolitis Trials

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2018 Trial Design and Baseline Characteristics

- Randomized 67 subjects at 6 sites in Israel with a 1:1 randomization between 160 ppm NO + supportive care (O₂ + hydration) and supportive care alone
- Subjects were 0-12 months old with acute bronchiolitis requiring hospitalization with at least 28 weeks of gestation
- PE (primary endpoint): the difference in hospital length of stay (LOS)
- SE (secondary endpoint): time to clinical improvement using the Modified Tal score (score ≥7 and <10 to enroll, ≤ 5 is goal)
- SE: the difference in time to SpO₂ of >92%
- SE: Safety (specifically NO₂ levels and methemoglobinemia) and Tolerability
- Treatment was five 30 minute sessions per day not to exceed 25 treatments
- All inhalations delivered by air/oxygen blender ±NO via a simple mask with a minimum FiO₂ of 21%

DATA PRESENTED AT THE SEPTEMBER 2018 EUROPEAN RESPIRATORY SOCIETY (ERS)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Std Treatment (N=34, Mean±SD)</th>
<th>NO + Std (N=33, Mean±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>21 M, 13 F</td>
<td>20 M, 13 F</td>
</tr>
<tr>
<td>Age (weeks)</td>
<td>16.72 ± 11.66</td>
<td>16.39 ± 11.7</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>5.88 ± 1.81</td>
<td>5.82 ± 1.79</td>
</tr>
<tr>
<td>Gestation Week</td>
<td>38.17 ± 1.82</td>
<td>38.25 ± 1.81</td>
</tr>
<tr>
<td>mTal Clinical Score</td>
<td>8.49 ± 1.02</td>
<td>8.45 ± 1.02</td>
</tr>
<tr>
<td>Vital Signs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temp.</td>
<td>37.37 ± 0.84</td>
<td>37.38 ± 0.85</td>
</tr>
<tr>
<td>BP (Sys/Dia)</td>
<td>101.0/58.0</td>
<td>101.0/57.6</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>148.5 ± 21.33</td>
<td>148.37 ± 21.24</td>
</tr>
<tr>
<td>Resp. Rate</td>
<td>56.85 ± 11.21</td>
<td>57.31 ± 11.08</td>
</tr>
<tr>
<td>% SpO₂ (Room Air)</td>
<td>88.54 ± 4.04</td>
<td>88.69 ± 3.98</td>
</tr>
</tbody>
</table>
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2018 Trial Results Presented at ERS 2018

Hospital length of Stay

- Primary endpoint of LOS calculated from enrollment to time of hospital discharge
- Welch’s t-test: p=0.085 – study was not powered for statistical significance

Oxygen Saturation

- Secondary endpoint of time to oxygen saturation of ≥92% calculated from enrollment
- Welch’s t-test: p=0.053

Pivotal Study in the US to Complete in 2Q21