Abstract P190 Table 1  

QVA149 versus placebo least squares mean (LSM) differences in FEV1 and FVC

<table>
<thead>
<tr>
<th>Visit</th>
<th>FEV1</th>
<th>FVC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30 min post-dose</td>
<td>60 min post-dose</td>
</tr>
<tr>
<td>Day 1</td>
<td>156 (14.2)</td>
<td>200 (16.9)</td>
</tr>
<tr>
<td>Week 3</td>
<td>255 (24.8)</td>
<td>275 (25.1)</td>
</tr>
<tr>
<td>Week 6</td>
<td>266 (26.2)</td>
<td>275 (27.2)</td>
</tr>
<tr>
<td>Week 12</td>
<td>236 (25.4)</td>
<td>260 (28.7)</td>
</tr>
<tr>
<td>Week 26</td>
<td>265 (31.5)</td>
<td>270 (29.6)</td>
</tr>
<tr>
<td>Week 39</td>
<td>240 (32.4)</td>
<td>286 (32.7)</td>
</tr>
<tr>
<td>Week 52</td>
<td>247 (33.3)</td>
<td>255 (33.6)</td>
</tr>
</tbody>
</table>

all p < 0.001

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Rajendra Mehta: he has no conflicts of interest.

P191  QVA149 ONCE DAILY IMPROVES EXERCISE TOLERANCE AND LUNG FUNCTION IN PATIENTS WITH MODERATE TO SEVERE COPD: THE BRIGHT STUDY

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Introduction  QVA149 is a novel once-daily fixed-dose combination of the long-acting β2-agonist indacaterol and the long-acting muscarinic antagonist glycopyrronium (NVA237) in development for the treatment of chronic obstructive pulmonary disease (COPD). The BRIGHT study evaluated the effects of QVA149 versus placebo and tiotropium on exercise tolerance and lung function in patients with moderate-to-severe COPD.

Methods  In a double-blind, double-dummy, 3-period crossover study, patients with moderate-to-severe COPD were randomised to QVA149 110/50 µg, placebo or tiotropium 18 µg once daily for 3 weeks. The primary endpoint was exercise endurance time for QVA149 versus placebo during a submaximal exercise tolerance test (METT) via cycle ergometry at Day 21. Dynamic inspiratory capacity (IC) at isotime during exercise, trough IC, trough FEV1, and trough forced vital capacity (FVC) were also measured.

Results  Eighty five patients were randomised; mean age was 62 years, mean post-bronchodilator FEV1 56% predicted. 86% patients completed the study. At Day 21, QVA149 significantly improved exercise endurance time by 59.5 seconds versus placebo (p=0.006), which was of a similar magnitude to the improvement seen with tiotropium versus placebo (66.3 seconds; p=0.002). More patients stopped exercise due to dyspnoea with placebo (43% versus 36% with both QVA149 and tiotropium) and due to muscle fatigue with QVA149 and tiotropium (44–46% versus 38% with placebo). QVA149 also produced significant and clinically meaningful improvements in trough FEV1, dynamic IC at exercise isotime, trough IC and trough FVC versus placebo and tiotropium (table).

Conclusion  QVA149 once daily provided significant and clinically meaningful improvements in exercise tolerance and lung function in patients with moderate-to-severe COPD. Despite superior bronchodilation demonstrated by QVA149 versus tiotropium, improvements seen in exercise endurance were similar, perhaps due to extra-pulmonary factors (muscle fatigue, ceiling effect). There were no safety concerns.

P192  QVA149 ONCE DAILY PROVIDES SUPERIOR BRONCHODILATION VERSUS INDACATEROL, GLYCOPHYRONIUM, TIOTROPIUM AND PLACEBO: THE SHINE STUDY

doi:10.1136/thoraxjnl-2012-202678.253

Introduction  QVA149 is a novel inhaled once-daily dual bronchodilator containing a fixed-dose combination of the long-acting β2-agonist indacaterol and the long-acting muscarinic antagonist NVA237 (glycopyrronium) in development for the maintenance treatment of COPD. This study evaluated the effect of QVA149 on
P191 QVA149 once daily improves exercise tolerance and lung function in patients with moderate to severe COPD: the BRIGHT study

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