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Title: QVA149 provides superior peak lung function in patients with COPD

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Body: Introduction Peak FEV₁ represents an objective endpoint to assess the effectiveness of bronchodilation in the morning when COPD symptoms are worst. Here we present peak FEV₁ results from the QVA149 SHINE and ILLUMINATE trials. Methods Both studies randomized patients (pts) ≥40 yrs with moderate-to-severe COPD to: QVA149 110/50µg, indacaterol (IND) 150µg, glycopyrronium (GLY) 50µg, placebo (PB; all via the Breezhaler® device) or open-label tiotropium (TIO), 18µg; via the Handihaler® device) (2:2:2:1:2) in the SHINE study; and QVA149 110/50µg or salmeterol/fluticasone (SFC) 50/500µg (via the Accuhaler® device) (1:1) in the ILLUMINATE study. Results The SHINE and ILLUMINATE studies randomized 2144 pts (89.1% completed) and 523 (82.6% completed), respectively. Least squares mean (LSM) difference for peak FEV₁ was statistically significant and clinically relevant for QVA149 vs. SFC on Day 1, Wk 12 and 26 (Table). QVA149 showed a statistically significant improvement vs. PB, IND, GLY and TIO for peak FEV₁ at Day 1, Wk 12 and 26 (Table).

Table: Peak FEV₁ (0-4h post-dose)

| | LSM treatment difference (SE) in mL* | | | | |
|-------|--------------------------------------|------------|------------|------------|------------|
| | SHINE | | | | ILLUMINATE |
| | QVA149–PB | QVA149–IND | QVA149–GLY | QVA149–TIO | QVA149–SFC |
| Day 1 | 210 (10) | 70 (8) | 30 (8) | 80 (8) | 70 (12) |
| Wk 12 | 310 (17) | 120 (13) | 130 (13) | 130 (13) | 150 (17) |
| Wk 26 | 330 (18) | 120 (14) | 130 (14) | 130 (14) | 150 (20) |

* for all values $p < 0.001$

Conclusion Once-daily QVA149 provided sustained, superior and clinically relevant improvements in peak FEV_1 and vs. IND, GLY, TIO, SFC and PB.